

MANAGING PATIENTS WITH DIABETES DISTRESS

A DNP SCHOLARLY PROJECT

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE

DEGREE OF DOCTOR OF NURSING PRACTICE

IN THE GRADUATE SCHOOL OF THE

TEXAS WOMAN'S UNIVERSITY

COLLEGE OF NURSING

BY

SWAPNA THOMAS, MS

NURS630331 DNP SCHOLARLY PROJECT

DR. MELANIE SMITH, DR. SABRENDA LITTLES, DR. MARIE TIETZE

07/28/2021

Table of Contents

Section I: Introduction of the Problem	4
Introduction/Background	4
Program Description	6
Organization	7
Inquiry Question	8
Purpose/Aim/Objectives	8
Needs Assessment and Problem	9
Theoretical/Conceptual Framework	13
Section II: Presentation of Evidence	15
Review of Evidence	15
Evidence Synthesis	18
Themes	18
Section III: Methodological Framework	19
Inquiry Question	19
Type of Project	19
Implementation Framework	19
QI model: MFI- PDSA	19
Data Analysis Plan	22
Data Collection Approach	24
Timeline	24
Operational Definitions	24
Data Evaluation Plan	26
Section IV: Findings/Results	27
Discussion/Conclusions	28
Timeline (Actual)	29
Outcome of Results	29
PAID-5 – Wilcoxon for Five Items Pre and Post	30
Qualitative Data: Thematic analysis	31
Being Normal	32
Useful Advice	33
Working on Better Coping Skills	34
Limitations	35
Section V: Recommendations and Implications for Practice	36

Relevant DNP Essentials, American Association of Colleges of Nursing (AACN, 2021)	38
Recommendations for Practice	40
Overall Project Summary	41
Next Steps	41
References	42
Appendix A: The Measure of Interest / Metric Needed	53
Appendix B: Evidence Table	54
Appendix C: SWOT Analysis	69
Appendix D: GANTT CHART	70
Appendix E: PAID-5 Questionnaire	71
Appendix F: CBT Session Talking Points	72
Appendix G: Data Collection Form	72
Appendix H: Graphs	75
Appendix I: Table of Themes and Validating Quotes	83
Appendix J: Permission to Use Table	85
Appendix K: IRB Certification	86

Managing Patients with Diabetes Distress: A Quality Improvement Project

Section I: Introduction of the Problem

Introduction/Background

Diabetes is the world's most prevalent metabolic disease and the leading cause of adult blindness, renal failure, heart disease, neuropathy, and the necessity for limb amputations (Barnes et al., 2020; De Boer et al., 2017; Das et al., 2020; Koye et al., 2018; Naranjo et al., 2020; Pop-Busui et al., 2017; Solomon et al., 2017). There are 34.2 million people (10.5% of the population) living with Type 2 Diabetes Mellitus (T2DM) in the United States. That number includes 26.9 million people diagnosed as well as 7.3 million undiagnosed (CDC, 2020).

Diabetes mellitus is a chronic disease causing a significant burden to the U.S population by causing increased morbidity and mortality. The resultant increase in emergency room visits and hospital admissions stresses the patient and the healthcare system. According to the American Diabetes Association (ADA), in 2018, diabetic patients incurred health care expenditures 2.3 times higher than those without diabetes (ADA, 2018). Additionally, indirect costs arose from effects of missed working days (\$3.3 billion), reduced productivity of those in the labor force (\$26.9 billion), those who were not in the labor force (\$2.3 billion), lost workdays due to disease-related disability (\$37.5 billion), and from 277,000 premature deaths directly resulting from diabetes (\$19.9 billion) (ADA, 2018). Diabetes was the 7th leading cause of death at an estimated 26.7 per 100,000 deaths in the U.S and 23.8 per 100,000 deaths in Texas that were attributed to diabetes in 2019 (CDC Wonder, 2019).

The Hispanic population in the U.S is disproportionately affected by diabetes mellitus type 2 (T2DM) due to socio-cultural factors such as low income, poor access to education and health care, genetic susceptibility to obesity, and higher insulin resistance (Aguayo-Mazzucato et

al., 2019) compared to the general population. In Texas, diabetes was the 4th leading cause of death in people of Hispanic race in 2019 (CDC Wonder data, 2019). Hispanic communities are affected more, as they have the highest uninsured rates among all races in the U.S at 16.7% (U.S. Census data, Keisler et al., 2020). Texas ranks 38th among the U.S states, with 12.2% of the population having diabetes. Around 18.4% of the population in Texas has no medical insurance, the majority of whom are Hispanic (America's Health Rankings Annual Report, 2020). The high prevalence of low health literacy and low health numeracy in this population further complicates the issue, leading to poor outcomes. Finally, diabetes affects not only the physical health and well-being of individuals but also affects their mental well-being.

Studies have shown that depression is a comorbid condition linked to diabetes. According to Pouwer et al. (2020), there is a bidirectional link between diabetes and depression, and the prevalence of depression in diabetic patients is twice that of the general population (Franco, 2018). Comorbid depression in diabetes leads to decreased productivity, poor quality of life, increased symptom burden, and functional disability. This leads to increased healthcare utilization, increased costs, and higher rates of mortality. Living with the diagnosis of diabetes also leads to worry, stress, frustration, and an increase in interpersonal conflicts. The phenomenon, identified as diabetes distress, has been shown to cause a negative emotional impact. It has also been associated with sub-optimal self-care and poor glycemic control (Dennick et al., 2017).

Studies have shown that distress from diabetes impairs medication adherence, a significant problem in around 50% of patients causing approximately 40% of the preventable deaths in the U.S (Edmondson et al., 2018), and an expenditure of 100 billion dollars in the U.S each year (Kleinsinger, 2018). Medication non-adherence in diseases like diabetes leads to poor

clinical outcomes and increases demands on healthcare services, setting in motion a vicious cycle. Diabetes distress is more directly associated with glycemic control than clinical depression (Aikens, 2012; Fisher et al., 2010; Leyva et al., 2011). In their study on a sample of patients attending low-income clinics, Pandit et al. (2014) found that diabetes distress was prevalent and linked to poorer adherence to health behaviors and glycemic control. Diabetes distress can be defined using the following themes: “distress associated with the burden of self-care; interpersonal issues; emotional burden and worry; relationships with caregivers and healthcare professionals” (Berry et al., 2015). Reducing diabetic distress is essential for proper management of diabetes and glycemic control (Hessler et al., 2014) and was the primary focus of this study.

Program Description

Untreated diabetes distress has been shown to lead to depression and premature death (Mathiesen et al., 2019). The American Diabetic Association (ADA) recommends routine monitoring of diabetic patients for diabetes distress when goals are unmet and at the onset of diabetes complications (Young-Hyman et al., 2016). Nurse practitioners are optimally positioned in the healthcare system to manage diabetes, screen for diabetes distress, and implement evidence-based interventions to address diabetes distress. Based on those recommendations, at a community healthcare clinic in Harris County, Texas, a nurse practitioner-driven intervention to identify and reduce diabetes distress and its associated complications in uninsured Hispanic patients was begun.

The clinic where the project took place had a comprehensive diabetes management program in place. Patients received care from a multidisciplinary team using a collaborative patient-centered approach for services, such as Diabetes Self-Management (DSM) education, nutrition education, ophthalmologic care, dental care, podiatric care, psychosocial care,

immunizations and health maintenance, etc. as recommended by the ADA (ADA, 2020, see Figure A). Although all patients receive this comprehensive care, several patients continued to present with poorly controlled diabetes. In light of the strong evidence about diabetes distress, a team decision was made to implement screening to evaluate diabetes distress as a possible cause of poor patient outcomes.

It is necessary to have evidence-based tools to identify patients with diabetes distress so that optimal management can be implemented to improve outcomes in diabetes. Several screening tools have been tested and tried with variable effects, and one of the highly recommended tools is the Problem Areas in Diabetes-5 (PAID-5) scale (Lee et al., 2015; Rariden et al., 2019) (Appendix E). It is of extreme importance to use screening tools like the PAID-5 scale (Perrin et al., 2017; Beléndez. et al., 2014) to identify this issue. Following the screening, interventions like Cognitive Behavioral Therapy (CBT) are proven methods to reduce diabetes distress to ensure optimal outcomes in this population (Lee et al., 2015; Li et al., 2018; Mathiesen et al., 2019; Ni et al., 2020; Perrin et al., 2019; Uchendu et al., 2017; Yang et al., 2020). According to Rariden et al. (2019) and Fisher et al. (2019), it is necessary to have meaningful clinician-patient conversations as a part of the therapy for diabetes distress. Patient-centered interventions with proven benefits can optimize outcomes in poorly controlled type 2 diabetic patients.

Organization

The setting was a community clinic that served the low-income, uninsured population of Harris County and surrounding counties. The clinic's mission is "To provide quality healthcare and education to those with limited access to such services in an environment which respects the dignity of each person" (San Jose Clinic website, 2020). On a microsystem level, the family

practice clinic was responsible for primary care and the care of chronic conditions. The department's staff consisted of doctors, nurse practitioners, licensed vocational nurses, and medical assistants. The clinic provides healthcare to minorities from low socio-economic backgrounds and the majority of the patient population is Hispanic. In this primary care clinic, though there was a comprehensive diabetes management program in place, the outcomes for T2DM were highly variable. Several patients presented with poorly controlled diabetes (around 50 patients per month on average), making them susceptible to adverse diabetes outcomes. The decision was made to screen for diabetes distress using the PAID-5 scale and to manage it using the CBT intervention specific for diabetes distress, thereby augmenting the existing care and improving diabetes outcomes in the clinic.

Inquiry Question

“Will screening patients with poorly controlled type 2 diabetes for diabetes distress and referral for and administration of a Cognitive Behavioral Therapy based intervention reduce diabetes distress and improve glycemic control?”

Purpose/Aim/Objectives

The project's purpose was to screen for diabetes distress and use the CBT intervention to improve outcomes in diabetes (reduced diabetes distress, improved glycemic control). The PAID-5 Screening instrument was used to assess diabetes distress in patients with Type 2 diabetes. Patients who screened positive for diabetes distress would be referred for CBT. The CBT intervention (one-hour individualized session administered by the behavioral therapy specialist) with follow-up would focus on empowering patients to make positive changes in self-care, improve medication adherence, improve dietary control, improve exercise, etc., and help them to develop better skills in managing their condition.

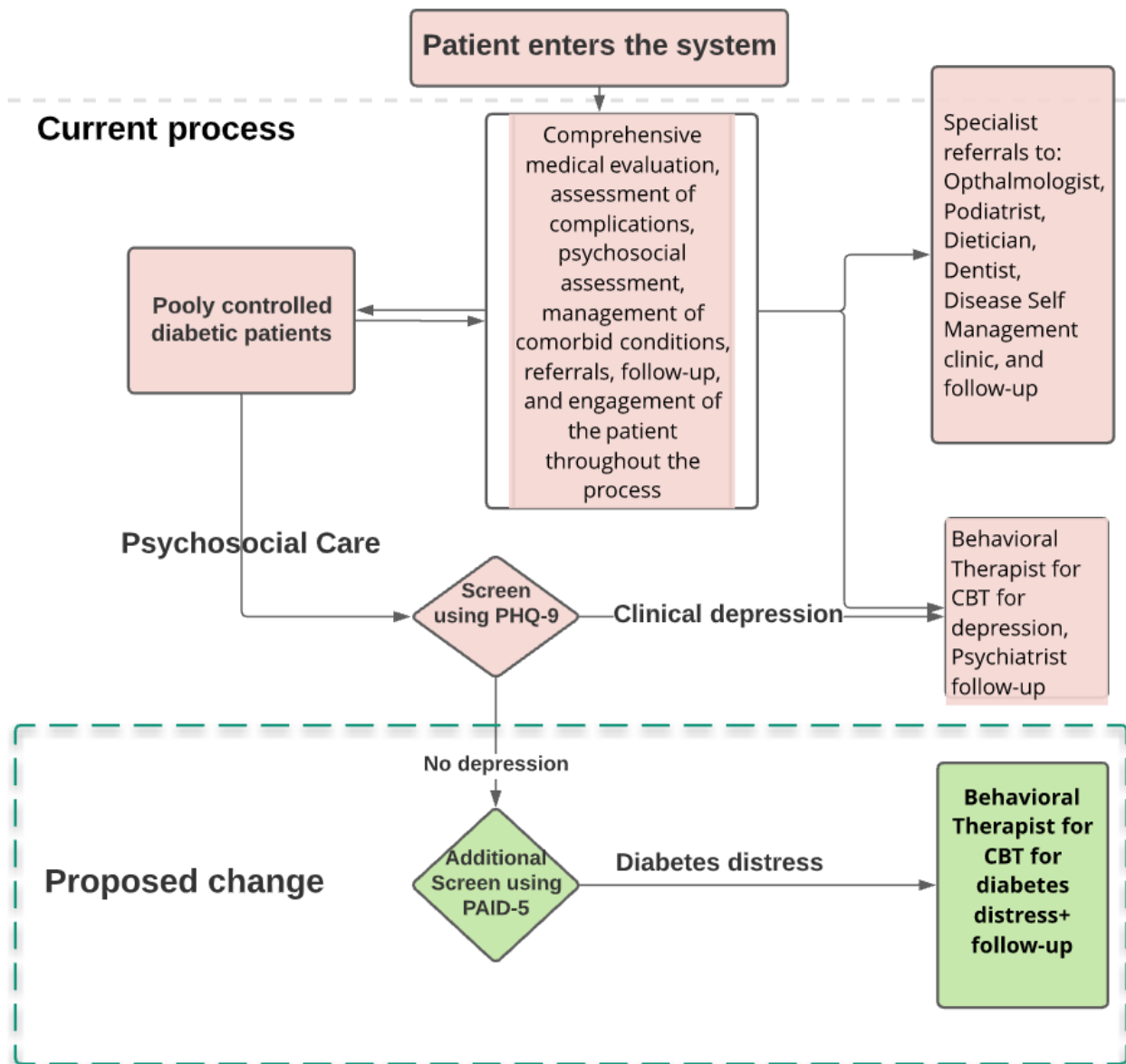
Needs Assessment and Problem

Though the clinic had a comprehensive management program for diabetic patients, the number of patients with poorly controlled diabetes was high as evidenced by data from pooled HbA1c reports from the previous year of 2020. According to the clinic pharmacist, diabetic patients had an estimated 58% medication adherence rate, which amounted to around 42% of the patients being non-adherent, as measured by refill rates. Of those who were adherent, approximately 60% still failed to reach their glycemic goals. The existing practice of managing T2DM involved regular follow-up based on the HbA1c levels, with most patients usually being seen at the clinic at least every three months. During clinician visits and Disease Self-Management (DSM) clinic visits, patients were taught to understand the importance of therapeutic goals and how they can achieve them. The usual goals are:

- HbA1c <7 %,
- fasting blood sugar 80-130 mg/dL,
- blood sugar two hours after meals <180 mg/dL,
- blood pressure <130/80 mm of Hg,
- body mass index <25,
- compliance with diet, medications, and
- lifestyle modifications.

Goals for HbA1c can be individualized, with comorbidities, age, and life expectancy taken into consideration, as recommended by the American Diabetic Association. Although good control is said to be achieved when HbA1c is below 7, a level of 8 and below is acceptable for those with multiple comorbidities according to the ADA guidelines (ADA, 2020).

During each visit, patients were screened with the Patient Health Questionnaire-9 (PHQ-9) screening tool. If the patients scored high on the PHQ-9 scale, they were referred to the behavioral therapist or psychiatrist as appropriate, and CBT or psychiatric care, and if needed, appropriate medications were prescribed. Patients were also referred to the DSM department, podiatrist, ophthalmologist, nephrologist, and other specialties as appropriate. The in-house pharmacy dispensed the needed medications at a nominal cost. Despite the services being available, the use of services was not optimal. This could be related to unidentified diabetes distress, an observation reinforced by the medical providers of the clinic which could potentially lead to uncontrolled diabetes and its associated adverse outcomes. Therefore, it was determined that it was extremely important to identify and address diabetes distress to optimize outcomes for these patients. The project proposed additional screening of T2DM patients using the PAID-5 instrument for identifying diabetes distress. Those found to screen positive would be referred for CBT, administered by the clinic's behavioral therapist. The T2DM patients for whom this project was conducted were adults aged 35 years and up, with the majority being married adults above 50. The PAID-5 instrument was found to be valid and reliable for use in similar populations. The new process flow is as shown in the diagram.

Figure 1*Process Flow Diagram*

A SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis (Appendix C) was done to assess current practice, understand what will and will not work for the organization, and to identify the specific steps needed to be undertaken (MindTools, n.d.). In their article Li et al. (2018) identified six interrelated organizational contextual features that influence the implementation of evidence-based practices within organizations; they are the culture of an

organization, its leadership, communication and networks, available resources, evaluation systems, monitoring and feedback processes, and champions.

Strengths identified on the SWOT analysis included the clinic leadership which was in favor of quality improvement projects and was engaged in and actively promoted activities to improve quality, and the organizational culture and climate were favorable for similar activities. The identified strengths included support from the medical director, clinic manager, administrators, and engaged specialists from different services. Experienced members of the team, access to the electronic health record and database, and a well-staffed clinic were additional strengths. Improving outcomes in diabetes was a priority of the organization which had support from the administration and the leadership team. The patient-centered nature of the project was an added strength and it was in alignment with the mission and the strategic goals of the clinic.

Some identified weaknesses included difficulty in meeting with team members due to conflicting schedules, staff being unclear of their role in the project, patients with multiple comorbidities, different needs and preferences, and patients with transportation issues. Identified opportunities included the potential for reducing errors and improving patient safety, the potential for increased patient satisfaction, and the potential for increasing compliance to the treatment regimen. Threats identified included the Corona Virus Disease-19 (COVID-19) pandemic which caused a direct and an indirect impact. The COVID-19 pandemic caused some decrease in clinic visits since COVID-19 positive cases or contacts resulted in appointment cancellations. During this period, telehealth and in-person visits were actively employed to keep providing services to the population. There were also the threats of telehealth-related technical issues, staffing shortages, etc.

Theoretical/Conceptual Framework

The project was guided by the patient-centered model of care and the organization's mission of providing quality healthcare and education to those having limited access to such services in an environment respecting the dignity of each person. Patient empowerment programs like this project were in perfect alignment with this mission. Theoretical frameworks that guided this project were the Health Promotion Model (HPM) and the Cognitive Behavioral Model (CBM). The HPM by Nola Pender, a holistic predictive model, posits that individuals are biopsychosocial creatures shaped by their environments and that they strive to create environments in which their human potentials can be fully expressed (Aqtam et al., 2018). According to Kurnia et al. (2017), approaches to the management of diabetes align with the HPM. There are several elements in this model which predict engagement in health promoting behaviors (Pender, 2011). According to Pender, the cognitive perceptual factors 'perceived benefits, perceived barriers, and self-efficacy' determine participation in health-promoting behaviors. There are modifying factors 'demographic characteristics, interpersonal influences, and behavioral factors' that interact to influence the cognitive-behavioral processes. The modifiable behavior-specific variables provide a rich source for providers for developing interventions and strategies. Empowerment strategies targeting the activity-related affect and interpersonal and situational influences can help facilitate and enhance the health-promoting behaviors of patients (Ho et al., 2010).

The Cognitive Behavioral model which further explains the links between depression/distress and T2DM (Moulton et al., 2015) is another theoretical basis behind the process. According to the Cognitive Behavioral model, our emotions are a product of our beliefs, evaluations, interpretations, and reactions to our daily life situations. In poorly controlled

diabetic patients, disruption of blood sugar control and diet control causes cognitive distortion and feelings of the futility of interventions and helplessness. This causes the patients to be non-adherent to treatment recommendations and the ensuing metabolic dysregulation aggravates the dysfunctional thoughts thus creating a vicious cycle. CBT facilitates the breaking of this vicious cycle by enabling the confrontation of the patients with their conflicts (Moulton et al., 2015). Here productive interactions are at play between an efficient care team and an informed and activated patient.

Section II: Presentation of Evidence

This quality improvement project screened poorly controlled T2DM patients with the PAID-5 scale to determine whether CBT-based intervention administered to those who screened positive would reduce diabetes distress and/or improve glycemic control.

Review of Evidence

There is a large body of literature showing the validity and reliability of the PAID-5 instrument's effectiveness in screening for diabetes distress. A meta-analysis examining studies from 17 different countries discovered that several of the studies used the PAID-5 scale in the study successfully to screen for diabetes distress (Perrin et al., 2017). Research findings have shown that CBT reduces diabetes distress and improves glycemic outcomes (Lee et al., 2015; Li et al., 2018; Ni et al., 2020; Perrin et al., 2019; Uchendu et al., 2017; Yang et al., 2020). For the selected review, randomized controlled trials (RCTs) and systematic reviews were utilized as below.

An extensive search for related literature published in English using the CINAHL, PubMed, Ovid, and Google Scholar databases for articles published after the year 2015 yielded more than 3000 studies from which 116 studies (RCTs and systematic reviews) were narrowed down and 15 were selected by manual evaluation for inclusion (Appendix B). Search terms used were type 2 diabetes, self-management, diabetic distress, PAID-5 scale, cognitive behavioral therapy, and glycemic control. A careful selection of studies that specifically addressed CBT in T2DM was made, and studies that exclusively included type 1 diabetic patients, children, and pregnant patients were omitted.

Research findings have shown good outcomes among diabetics following the implementation of CBT. The Diabetes Motivation Strengthening (DIAMOS) was a

diabetes-specific CBT program used in an RCT where the effects of the intervention on diabetic patients with subclinical depression caused a reduction in depressive symptoms and diabetes distress (Hermanns, 2015). It was also found to be helpful in the prevention of advancement to major depression. Huang et al. (2016) conducted a study to explore the use of Cognitive Behavioral Therapy. In their study, the intervention resulted in a significant improvement in glycemic control, psychological adjustment, and health-related quality of life. In the study by Newby et al. (2017), internet-based CBT (iCBT) was found to be useful for reducing diabetes distress as measured by the PAID-5 scale. They noted that iCBT is an efficient treatment option for people with diabetes and depressive symptoms. In the RCT of nurse-led education and CBT intervention done by Wiltehead et al. (2017), there was a significant improvement in HbA1c levels at six months after the intervention. In the RCT done by Noroozi et al. (2017) where a group CBT intervention was employed in type 2 diabetic patients, a reduction in depressive symptoms and an improvement in quality of life were noted. In the CBT and social networking intervention trial done by Alanzi et al. (2018), improvement in glycemic control was noted as evidenced by improved HbA1c levels post- intervention. In the RCT by Wroe et al. (2018), the cognitive therapy intervention in diabetic patients resulted in an improvement in self-management and glycemic control. In the mindfulness intervention "Individual Mindfulness-Based Cognitive Therapy" done in diabetic patients as part of a pilot RCT, patients who received the intervention had significantly reduced diabetes distress, and improved attention regulation (Schroevers, et al., 2015).

In the Diabetes and Depression (DAD) study, a randomized controlled trial by Petrak et al. (2015) where the effect of Sertraline and CBT on outcomes in diabetes were assessed, authors recommended using the therapies together in trying to achieve improved glycemic control and

reduction in depressive symptoms. As opposed to other studies, in this study CBT or Sertraline delivered as a single treatment was found to be insufficient in treating patients with poor glycemic control and depression. In the peer-delivered CBT intervention targeting functional improvement in diabetic patients in the RCT by Andrea et al. (2020), improvement in pain levels, functioning, self-reported physical activity, and quality of life was noted in the intervention group, but there was no significant change in physiologic measures. In the systematic review by Uchendu et al. (2017), CBT was found to be effective in improving glycemic control both short-term and medium-term. The effect on long-term glycemic control was not significant, and there was a mixed effect of CBT on diabetes-related distress and quality of life. In the meta-analysis of RCTs by Yang et al (2020), the results of the main analysis showed that CBT-based interventions reduced HbA1c levels and depression symptoms significantly and improved psychological outcomes. In the meta-analysis of interventions for the treatment of diabetes Perrin et al. (2019), an analysis of interventions in 32 studies demonstrated that psychoeducational interventions were effective in the treatment of diabetes distress and for improving glycemic control. Schmidt et al. (2018) conducted a systematic review and meta-analysis of 394 articles where screening for diabetes distress using validated scales like the PAID-5 scale and treating those who were found to have diabetes distress with psychological interventions was done. In their review and analysis, diabetes-tailored psychological interventions were found to be effective in reducing HbA1c. In the RCT by Cummings et al. (2019), tailored CBT along with lifestyle counseling administered to T2DM patients with comorbid depression and/or regimen-related distress improved medication adherence, self-care behaviors, and glycemic control while reducing depressive symptoms and regimen-related distress.

Evidence Synthesis

The review of studies showed strong evidence for the validity and usability of CBT for the management of diabetes distress and for improving glycemic control. There were 15 studies identified (12 RCTs and 3 Systematic reviews with meta-analyses) that used CBT for the management of the issue, and all the studies provided strong evidence at the level IA-1B. All the studies used CBT interventions to tackle poor diabetes control, and CBT positively impacted diabetes control and reduced depression. They recommended using the CBT either as a single intervention or in combination with other interventions to achieve optimal outcomes. The recommendation was to tailor culturally congruent CBT interventions based on the population at hand. Studies previously done in similar groups also have suggested an individualized approach (Rustveld et al., 2009).

Themes

- Diabetes distress can lead to poor outcomes and premature death in patients with T2DM (Berry et al., 2015; ADA, 2018).
- Screening for diabetes distress using validated tools and referral for psychosocial care are advised (Young-Hyman et al., 2016; ADA, 2021).
- CBT helps reduce diabetes distress (Newby et al., 2017; Perrin et al., 2019; Uchendu et al., 2017; Yang et al., 2020; Hermanns et al., 2015; Noroozi et al., 2017; Petrak et al., 2015; Schroevers et al., 2015).
- CBT prevents the progression of diabetes distress to depression (Hermanns et al., 2015)
- Better glycemic control and psychological adjustment after CBT and follow up (Huang et al., 2016; Newby et al., 2017; Wroe et al., 2018; Whitehead et al., 2017; Alanzi et al., 2018; Andrea et al., 2020; Schmidt et al., 2018; Cummings et al., 2019).

Section III: Methodological Framework

The Model For Improvement (MFI) - Plan –Do- Study- Act (PDSA) framework was used in this intervention. The data collection method will have minimal impact on the daily processes of the clinic. The project goals align with the organization’s mission of providing quality healthcare and education to those with limited access to such services.

Inquiry Question

“Will screening patients with poorly controlled type 2 diabetes for diabetes distress and referral for and administration of a Cognitive Behavioral Therapy based intervention reduce diabetes distress and improve glycemic control?”

Type of Project

The proposed project is a Quality Improvement (QI) project with a plan to identify diabetes distress in diabetic patients with poor glycemic control and to facilitate improvement in glycemic control through screening using the PAID-5 instrument and administration of CBT. There would be no additional cost to the clinic as this involves the use of existing resources for the improvement of current processes.

Implementation Framework

QI model: MFI- PDSA

The MFI-PDSA model has three key questions as to its basis.

1. What are we trying to accomplish? There are no processes currently in place in the clinic to address diabetes distress. Priority is given to gaps/needs within the system, and improving patient outcomes is a top priority, with diabetes distress and/or depression being one of the major barriers to achieving optimal outcomes. This project is truly relevant in that it includes patients’ preferences for care, identifies barriers, and promotes

education about the disease process. It increases patient safety by increasing patient engagement and increasing communication between providers and staff regarding patient care issues.

2. How will we know that a change is an improvement? It will be determined if the change is an improvement by measuring the outcomes. The outcomes will be studied and evaluated to determine whether or not there was any improvement. The benefits of using self-report scales and the behavior modification approach using cognitive behavioral therapy are immense and there are no risks expected. The clinic where this project was conducted already uses cognitive behavioral therapy to treat depression and has specialists addressing the issue. The goal is to add CBT intervention specifically targeting the reduction of diabetic distress and improvement of outcomes in T2DM.
3. What changes can we make that will result in improvement? (Langley et al., 2009). Changes include incorporation of the PAID-5 scale, a referral process, and the administration of CBT by a trained specialist provider. The screening will use the PAID-5 scale and data will be collected. Outcomes will be scores in the PAID scale and glycemic control using fasting blood sugars and HbA1C levels. Those who have had the sessions completed can be followed up further either by the medical provider or the behavioral therapy specialist based on the specific behavioral issue identified and will be tracked by measuring outcomes (blood glucose levels, HbA1C levels, PAID-5 scale scores, etc.) in subsequent visits (Appendix A).

These three key questions then connect to the Plan-Do-Study-Act (PDSA) cycle.

During the “Plan” stage, the needs assessment was done, a problem was identified meriting attention in the chosen population, and a SWOT analysis was done. The plan for the

intervention and the change idea was made, and a business case was made. The project team was identified, and measures were decided upon and a plan for the collection of data was made. A Gantt chart was used for tracking the timeline. The project team met and planned on screening the patients for diabetes distress using the PAID -5 scale and plans for administering the optimal intervention were made. The plan was to provide cognitive behavioral therapy individualized to the patient as the population and the culture necessitates a culturally congruent approach. This will ultimately result in improvement in glycemic control and reduction in diabetes distress.

During the “Do” stage, the plan was tested out on a small scale. Data collection was done, and observations were made. The PAID-5 questionnaire was administered to diabetic patients who had at least one HbA1c with a value equal to or above 8 within the past year, based on the inclusion and exclusion criteria. It was anticipated that around 100% of the patients would complete the scale since it is administered as a pre-visit screening measure. Of these, 50% will likely qualify and have at least one session of CBT. The HbA1c was planned to be measured every 3 months or as appropriate. Patients were also asked to log their blood sugar values and bring them to the clinic each visit. These goals were measurable and felt to be achievable, and it took around three months for the initial project cycle.

The addition of CBT sessions was economical since it did not cost the clinic any extra expenses as it made use of the existing facilities and staff. Those who qualified for the CBT were referred for the session with the therapist. The CBT intervention is patient-centered, designed to challenge unhelpful beliefs, and relevant in that it identified and addressed the behavioral component of the existing barriers (Hadler et al., 2020). The positive patient-provider relationship which develops can further contribute to a reduction in diabetes distress and improvement in glycemic control (Skinner et al., 2020).

Though time to complete the questionnaire could have been a factor that impacted the appointment duration for patients and workflow of staff, the presence of specialists with expertise with enough time slots available minimized this problem. Teaching the staff how to facilitate administering the questionnaire to the eligible patients was done to ensure a smooth process. Furthermore, the PAID-5 instrument used for screening is simple and takes less than 10 minutes to complete, and the CBT session took around one hour, as administered by the experienced behavioral therapy specialist. Talking points (Appendix F) were used to guide the discussion as recommended by experts in the field of CBT for diabetes distress (Rariden, 2019; Fisher, et al., 2019).

In the “Study” stage primary outcomes were monitored, measured, and documented. Appropriate measures as stated in the measurement section were used. Changes in glycemic control as measured by fasting blood sugar levels and HbA1c levels, and changes in diabetes distress as measured by the PAID-5 scale were studied.

During the “Act” stage, the determination of needed modifications, and the decision whether to adapt, adopt, or abandon the intervention was made. Modifications were made based on the information yielded from the study phase by close monitoring. Based on the findings, recommendations were made regarding the necessary changes. Re-evaluation is planned to be done periodically using 90-day rapid cycles and the project will be adapted to provide ongoing quality improvement, to a larger group with the necessary changes incorporated.

Data Analysis Plan

In addition to the PAID-5 scores pre and post-intervention, data collected included patient demographics using a demographic tool (Appendix G), fasting blood sugars, and laboratory test results (HbA1c). The use of the PHQ 9 instrument was found to be inadequate to identify

diabetes distress as seen from the study by Wardian et al. (2019), where even though 70.4% of patients screened negative for depression, they scored high on at least one domain for diabetes distress. These researchers recommended regular screening for diabetes distress to prevent poor outcomes. They noted that while diabetes increases patients' risk for depression, rates of diabetes distress can be much higher. The use of measures specific to diabetes distress is essential to properly screen and identify those with diabetes distress. The project used the PAID-5 Scale which has shown reliability and validity in similar patient populations.

The PAID-5 has been found to have a sensitivity of 94% and specificity of 89% in recognizing diabetes-related emotional distress (McGuire et al., 2010). In a systematic review by Lee et al. (2015) comparing the effectiveness of instruments measuring diabetes distress, the PAID scale was found to be the most frequently used and the best validated. The Spanish version of the PAID scale has been proven reliable and valid with good psychometric properties (Welch et al., 2007; Schmitt et al., 2016). Beléndez et al. (2014) measured diabetes-specific emotional problems in 173 Hispanic adults from Spain with diabetes using the Spanish version of the PAID scale and found that the scale was reliable and valid for measuring diabetes distress. In the Community health workers assisting Latinos manage stress and diabetes (CALMS-D) trial done in 102 Latino type 2 diabetic patients, the Spanish version of the PAID-5 scale was used effectively to measure diabetes distress (Bermúdez-Millán et al., 2016). In the current project, the scale was administered to all adults above 35 years with poorly controlled type 2 diabetes (previous HbA1c values more than or equal to 8 measured in at least one of the latest lab results within the past year). Type 1 diabetic patients, patients with multiple comorbid conditions, patients with heart failure, patients with psychiatric disorders, patients with history of alcohol or substance abuse, and critically ill patients were excluded.

Data Collection Approach

PAID-5 scores: The project screened poorly controlled T2DM patients who met inclusion criteria with an HbA1c of 8 or above using the PAID-5 instrument for identifying diabetes distress. Those found to screen positive with a score equal to or above 8 were referred for CBT. The values were collected using a specially designed data collection form (Appendix G) and were later copied to the excel spreadsheet, and analyzed using the IBM SPSS version 26.

HbA1c values: Poorly controlled type 2 diabetic patients with a pre-intervention HbA1c of 8 or above and scores on the PAID-5 instrument of 8 or above were referred for CBT. Those who underwent CBT were tracked for their post-intervention HbA1c values next visit in around 3 months. The values were collected using the data collection form which was later copied to the excel spreadsheet and was analyzed using SPSS.

Fasting blood sugar values: The ADA recommends a target fasting blood sugar of 80-130 mg/dL for non-pregnant patients with diabetes (ADA, 2020). Fasting blood sugar values of patients were collected pre- and post-intervention. The values were collected using the data collection form and were later copied to the excel spreadsheet and analyzed using SPSS.

Timeline

The project was designed as a screening, intervention, and follow-up, with a pre-post design. The problem identification was done in September 2020, followed by planning for the intervention, team formation, and obtaining approval. The project spanned over 3 months from February 2021 to April 2021 (see Gantt chart, Appendix D).

Operational Definitions

Variables for the “Population, Intervention, Comparison, Outcomes, and Time (PICOT) sections were identified and operational definitions were drafted (see Table 1).

Table 1*Operational Definitions*

Variables	Operational Definition
Population (P) – Patients with poorly controlled type 2 diabetes	The number of patients who present with HbA1C >8 attending the community clinic.
Intervention (I) - screening with the PAID-5 scale, and referral for and administration of a Cognitive Behavioral Therapy based intervention	Administration of the PAID-5 scale and identification of patients with diabetes distress. Referral for and administration of cognitive behavioral therapy.
PAID-5 scale	Problem Areas in Diabetes Scale 5 (PAID-5), a tool for screening diabetes distress comprising five emotional-distress questions.
Cognitive Behavioral therapy	A therapy addressing both the psychological and adherence issues that are important to overall well-being in people with diabetes (American Psychological Association, 2015).
Comparison (C) – Traditional management	The existing management before the intervention.
Outcomes (O) -	
Diabetes distress	“An emotional state in diabetic patients that causes significant emotional distress but does not meet the qualifications for major depressive disorder” (Kreider, 2017).
Change in glycemic control:	“The difference in HbA1C value from baseline to the end of the project (Petrak et al., 2013)”. Also, the change in fasting blood sugar ranges from the baseline to the end of the project.
HbA1C levels	The glycosylated hemoglobin values between pre-and post-intervention.
Fasting blood sugar values	The fasting blood sugar values between pre-and post-intervention.
Time (T) - over a period of 3 months	February 2021 through April 2021

Data Evaluation Plan

The screening and CBT were integrated into the clinic workflow. Methods and metrics used for the evaluation of the QI project can be found in the metrics table in the appendix. Outcome measures were scores on the PAID-5 scale, HbA1c levels, and fasting blood glucose levels. The percentage of patients who completed the intervention and followed up later was the process measure. The data were analyzed using statistical software with expert help from the Statistics faculty.

Being a quality improvement project, the project team met periodically and planned changes to the steps or metrics to achieve the desired effect for those areas found to be failing and/ or not working as intended. In the future, lessons will be learned from any setbacks and PDSA cycles will be rerun until optimal outcomes are achieved. Based on feedback from the team, the project will be periodically modified to ensure its success. The project contributed to nursing knowledge by filling in gaps and validating and testing knowledge that is already available about the usefulness of CBT in understanding and caring for patients affected with chronic conditions like T2DM.

Section IV: Findings/Results

Statistical analyses were performed using the computer-based analysis program Statistical Package for the Social Sciences (SPSS) software (Pallant, 2020). Statistical significance was set at $p \leq 0.05$. Demographic variables were summarized by descriptive statistics (see Figure 2).

Figure 2

Characteristics of the Sample

	N=16	% Of Sample
Gender		
Female	11	68.8
Male	5	31.3
Age		
35-44	2	12.5
45-54	6	37.5
55-64	6	37.5
≥ 65	2	12.5
Ethnic or racial group		
Black or African	3	18.8
Hispanic or Latino	12	75.0
Asian or Pacific Islander	1	6.3
Marital/relationship status		
Married	9	56.3
Divorced	3	18.8
Single	3	18.8
Unknown	1	6.3
Education level		
College	2	12.5
High school	8	50
Middle school	6	37.5
Living arrangements		
Alone	1	6.3
Family	13	81.3
Non-family	2	12.5

Forty-one patients with an HbA1c value of 8 or more were screened with the PAID-5 scale and they were referred for the intervention based on a high score of 16. The mean duration of diabetes was 16.5 years. Out of the 16 patients who were referred for CBT, 11 (68.8%) were female and 5 (31.3%) were male. Ages ranged from 35 to 65 years with a mean age of 53.9

years. Out of the participants, 12 (75%) were Hispanic, while one (6.3%) was Asian, and three were Black (18.8%). Most of the respondents were in the married category (56.3%). There were three single patients (18.8%), three divorced patients (18.8%), and one patient with unknown marital status (6.3%). Most of the patients belonged to the high school completed category, while two (12.5%) were college-educated, and six (37.5%) had completed middle school. Thirteen (81.3%) of the patients lived with their families, while one patient (6.3%) lived alone, and two patients (12.5%) lived with non-family members (Appendix H).

Discussion/Conclusions

The evaluation of outcomes was done in the five dimensions: reach, efficacy, adoption, implementation, and maintenance, according to the RE-AIM framework (<https://www.re-aim.org>; Carljford et al., 2012). Reach measures the proportion of individuals who participated in the program. The total number of patients who were screened was 41 and of those who were referred for the intervention based on scores was 16. Effectiveness measured the effect on the patient's qualitative and quantitative outcomes, captured using labs and follow-up interviews. Adoption at the setting level was the number of patients who attended the intervention after being referred for CBT, which was 14 out of 16 (87.5%). Being able to maintain fidelity to the intervention is assessed by the implementation domain, which proved to be successfully done with fidelity to the original idea maintained. Maintenance refers to the sustaining of the project in the clinic long-term, which was determined by the overall effectiveness and feasibility. In the clinic, plans for maintenance and long-term sustainability have been made.

In this project, following the holistic predictive model of HPM, the healthcare providers were able to understand and address modifiable behavior-specific variables which influence

diabetes distress. Application of the model provided evidence for the effectiveness of screening for diabetes distress and application of the CBT. The patients acknowledged competing demands and committed to a plan of action. Patients' diabetes distress levels significantly reduced, outcomes in diabetes improved, and healthy lifestyles were promoted thus preventing further complications. This will in turn reduce the economic impact of diabetes-related complications on the healthcare system.

Timeline (Actual)

The project was conducted using a pre-post design. The actual project spanned over 3 months from February 2021 to the end of April 2021 (see Gantt chart, Appendix D). One PDSA cycle was completed, and successive cycles were planned.

Outcome of Results

After evaluating the post-intervention test statistics, it was discovered that the project yielded some statistically significant improvements. A Wilcoxon signed-rank test showed that in those patients with existing diabetes distress who underwent screening using the PAID-5 scale and the CBT intervention ($n=14$), a statistically significant change in HbA1c levels ($Z = -2.668$, $p = 0.008$); and PAID-5 score levels ($Z = -2.100$, $p = 0.036$) was elicited. While the median fasting blood sugar levels improved, the change did not reach significance ($Z = -1.538$, $p = 0.124$) (Appendix H).

The Wilcoxon signed-rank test showed that in those patients with existing diabetes distress who underwent screening using the PAID-5 scale and the CBT intervention, the median values for the HbA1c levels decreased with a large effect size (.597). The value of the median PAID-5 scores also decreased, with a medium effect size (.397) as seen in the tables (Table 2;

Table 3). The change elicited in PAID-5 score levels was highest for Q3 worry ($Z = -2.395$) with an effect size of 0.453 (medium).

Table 2

Median for Key Variables

Statistics							
		PAID-5 score Pre	PAID-5 score Post	HbA1C Pre	HbA1C Post	Fasting BS1	Fasting BS2
N	Valid	16	10	16	5	16	14
	Missing	0	6	0	11	0	2
Percentiles	25	9.25	3.50	8.900	8.350	120.00	108.75
	50	13.00	7.00	9.850	8.800	156.00	123.00
	75	14.00	12.25	12.050	11.050	198.75	161.00

Table 3

Effect Size for each Key Variable and the PAID-5 Items

<p>PAID-5 Score Pre and Post [observation = 14 X 2]</p> <p>Wilcoxon Z / sqrt of N</p> <p>2.100 / sqrt of 28</p> <p>2.100 / 5.292</p> <p>0.397 [medium effect size]</p>	<p>HbA1c Pre and Post [observation = 10 X 2]</p> <p>Wilcoxon Z / sqrt of N</p> <p>2.668 / sqrt of 20</p> <p>2.668 / 4.472</p> <p>0.597 [large effect size]</p>	<p>PAID-5 Score Pre and Post for Q3 Worry Future [observation = 14 X 2]</p> <p>Wilcoxon Z / sqrt of N</p> <p>2.395sqrt of 28</p> <p>2.395 / 5.292</p> <p>0.453 [medium effect size]</p>
---	---	--

PAID-5 – Wilcoxon for Five Items Pre and Post

According to the Wilcoxon signed-rank test, in those patients with existing diabetes distress who underwent screening using the PAID-5 scale and the CBT intervention ($n=14$), the change elicited in PAID-5 score levels was highest for Q3 worry ($Z = -2.395$, $p = .017$) as shown below in Figure 3.

Figure 3*Wilcoxon Significant Results*

Wilcoxon Test for Each Individual PAID-5 Survey Item ^a					
	PAID-5 Q1 Scared Post - PAID-5 Q1 Scared Pre	PAID-5 Q2 Depressed Post - PAID-5 Q2 Depressed Pre	PAID-5 Q3 Worry Future Post - PAID-5 Q3 Worry Future Pre	PAID-5 Q4 Take Too Much Energy Post - PAID-5 Q4 Take Too Much Energy Pre	PAID-5 Q5 Coping Complications Post - PAID-5 Q5 Coping Complications Pre
Z	-.633 ^b	-1.692 ^b	-2.395 ^b	-1.634 ^b	-1.567 ^b
Asymp. Sig. (2-tailed)	.527	.091	.017	.102	.117
a. Wilcoxon Signed Ranks Test					
b. Based on positive ranks.					

Qualitative Data: Thematic analysis

To better understand the process of improvement, we completed a follow-up telephone call post-completed intervention (screening, CBT sessions). Fourteen of the 16 patients did respond to the telephone contact. The DNP student transcribed notes from the telephone calls to the Excel spreadsheet. Additionally, there were transcribed notes from the cognitive behavioral therapist during the planning, the review of scores from the screenings, and after the therapist conducted the sessions. There were five statements in the PAID-5 screening tool which was described by the therapist and DNP student as important to begin the conversation for the 1:1 session with the therapist. Specifically, patients responded to five statements focused on the following:

- Feeling scared when you think about living with diabetes;
 - Feeling depressed when you think about living with diabetes;
 - Worrying about the future and the possibility of serious complications;
 - Feeling that diabetes is taking up too much of your mental and physical energy every day;
- and
- Coping with the complications of diabetes.

The patients were asked to score each item from 0 (no problem) to 4 (serious problem). Each patient's score for each item and the total score were reviewed by the DNP student and the therapist. This information provided baseline information addressed during the CBT sessions. Transcripts were reviewed by the DNP team and themes were formulated from the transcripts according to a thematic analysis framework by Braun et al. (2006). Specifically, the steps followed in using this technique include familiarization, coding, generating themes, reviewing themes, and defining and naming themes. Familiarizing included frequent reviews of the transcribed notes to begin processing words, phrases that stood out in the document. Coding and generating themes involved returning to the notes and highlighting what emerged as patterns that were repeated from patient to patient. Each team member developed their list of themes from the coding and patterns for further definition and naming of the themes (Braun et al., 2006). Once a list was generated, to include quotes that were salient for each theme, the DNP team met to discuss and come to a consensus. Several themes emerged when combining both team members' analyses from their ongoing familiarizing of the notes. Three themes were agreed upon: Being normal, Useful advice, and Working on better coping skills. Each of the themes is described with relevant excerpts from the transcribed note to validate the theme (See Table 4).

Being Normal

Patients described the importance of someone listening to their stories and providing validation of their experience. Believing that their experience was to be expected provided the patient a sense of comfort and possibly relief. These feelings could enhance their ability to set goals for themselves, knowing that trying to better manage their diabetes takes time and support. Patients shared their need to change their attitude towards the disease and recognized that it was normal to feel the way they felt, think positively, not worry unnecessarily, redirect negative

feelings, and take one day at a time. Moreover, patients communicated that they were able to talk in detail about their problems, and discussing their issues helped in relieving their stress and stated that it was a welcome change from being always told what to do. Patients also shared that they started seeking family support, through positive interactions. The therapist's work with patients reinforced this theme through her intentional focus on open communication through listening for meaning, and the value patients placed on their unique responses to their diagnosis and management. Research supports that starting the conversation can be facilitated by using screening tools such as the PAID-5. Specifically, research purported that alerting physicians to the results of completed PAID questionnaires improved patient satisfaction and PAID scores after three and six months. This research showed that engaging patients in a conversation with their providers decreased DM-specific distress (Jackson & Kroenke, 2001; Rao, Weinberger, & Kroenke, 2000).

Useful Advice

Patients reported that the therapist and CBT sessions provided opportunities to learn new ways for coping by reviewing strategies that were practical and could be applied regularly. Specifically, patients shared that they could use the information to help them feel better about controlling their diabetes and using clinic and community resources to further support managing their distress. Useful advice addressed all items on the PAID-5 screening tool, helping patients to better plan their future by anticipating potential problems they may encounter (stressful day at work, financial challenges, etc.). Being keen to appreciate the patients' unique response, the therapist shared advice that was specific to each patients' response, reporting how important the screening tool and collaboration with the DNP student were essential to meaningful interactions, and tailored recommendations and strategies.

Working on Better Coping Skills

This theme resonated with patients through their sharing that the sessions increased their motivation for following specific recommendations including making better food choices, regularly exercising, setting short-term and long-term goals, taking prescribed medications, and making sure to keep scheduled appointments with their providers. The therapist shared that ‘useful advice’ guided coping skills were shared and reviewed with the patients. Specifically, the therapist used reflective communication to better appreciate each patient’s perception of their experience. Again, using the screening tool and collaboration with the DNP student reinforced the significance of timely, and relevant information sharing.

An interview with the behavioral therapist was conducted which added another perspective that shed more light on the CBT intervention. All of the patients acknowledged their need to monitor their diabetes closely and to follow the medical providers recommendations, but verbalized increased stress from the added responsibility. They admitted to failing in several aspects and not being able to follow recommendations. This was creating a vicious cycle of guilt, unhealthy eating, metabolic dysregulation, and increased stress. The therapist probed the positive and negative factors that impacted their diabetes care. The majority of the patients responded that it was food that impacted their diabetes care leading to distress the most. Others listed inability to exercise, sexual dysfunction from diabetes, etc. All the patients were concerned about the current and future impact of uncontrolled diabetes on their health. Behavioral health provider’s perspective: Being of the same Hispanic background, helped the provider with facilitating interaction and conversation. The session was extremely helpful in identifying and addressing dysfunctional thoughts, setting goals, and guiding/navigating the patients to their desired health goals.

Limitations

The project population only included low-income uninsured diabetic patients from an inner-city area, the majority of whom were Hispanic in origin. Social response bias is another possible issue that may have affected the screening results, as the patients may have consciously altered the answers to provide ‘normal’ answers. The findings may also be treatment or disorder-specific for diabetes distress. The relatively small size of the project population was one limitation that may have resulted in an increase in the margin of error. The short time frame of three months is another limitation and a longer period of study with consecutive PDSA cycles is recommended.

Section V: Recommendations and Implications for Practice

Sustaining improvement from evidence-based practice projects similar to the current one necessitates the consideration of the cost-benefit ratio. The triple Aim Framework from the Institute for Healthcare Improvement (IHI) with the goals of “improving patient experience, improving the overall population health of Americans, and decreasing the per capita cost of health care” (IHI, nd), is useful in considering costs. These goals are vital to the national strategy of healthcare reform which resulted from the Affordable care Act (ACA) signed into law by President Obama in 2010. A summary of the PICOT-related project results and associated proposed practice improvement is depicted in Table 4.

Table 4*Project Results Summary and Next Steps [Green = post-CBT change noted]*

Measure	Test/Evaluation	Result	Practice-Related Improvement
Change in <i>overall</i> diabetes distress via PAID-5 [pre-post-CBT implementation]	Wilcoxon Ranked Test	Statistically significant difference $Z = -2.668$, $p = 0.008$	Continue to screen all patients with diabetes using the PAID-5
Change in <i>individual</i> diabetes distress via PAID-5 [pre-post-CBT implementation]	Wilcoxon Ranked Test	Statistically significant difference for “Worrying about the future and the possibility of serious complications” $Z = -2.395$, $p = .017$	For each patient, assess and address the “worrying” contribution to stress
Change in glycemic control via HbA1c [pre-post-CBT implementation]	Wilcoxon Ranked Test	Statistically significant difference $Z = -2.668$, $p = .008$	Utilize assessment of distress via PAID-5 and prioritize patients with 8 or above score for CBT
Change in FBS [pre-post-CBT implementation]	Wilcoxon Ranked Test	No statistically significant difference $Z = -1.538$, $p = .124$	Continue to monitor but the main focus should be on HbA1c trends

Open-ended survey responses about CBT, post CBT program	Themes from the anecdotal comments were evaluated for comparison and trends	Themes identified “Being normal” “Useful advice” “Working on better coping skills”	Focus CBT programs to cover these patient concerns
---	---	--	--

The screening and intervention have been adopted and will be periodically adapted based on the findings, for process improvement. The patient experiences from the processes of screening, referral to cognitive behavioral therapy, and follow-up telephone calls were evaluated and recommendations for future improvement were developed, which will be addressed. The use of a cost-effectiveness analysis (CEA) methodology would be useful for sustaining the screening guidelines and management of patients at high risk for diabetes distress. To continue providing this additional intervention while trying to sustain this project, the clinic will also likely need more staff training, more time allocated with the cognitive-behavioral therapist, and more support staff to assist with the follow-up telephone calls.

Relevant DNP Essentials, American Association of Colleges of Nursing (AACN, 2021)

1. DNP Essential I. Scientific Underpinnings for Practice

This DNP essential was demonstrated when the comprehensive review and synthesis of the relevant scientific literature, evaluation using the appropriate tool, and developing the data further for inclusion in the project were done.

2. DNP Essential II. Organizational and Systems Leadership for Quality Improvement and Synthesis Thinking

This DNP essential was demonstrated when a gap/SWOT analysis was conducted, followed by the discussion of the plan with the leadership team. It was also demonstrated when the DNP student took the role of the project manager, developed the business case, attended the project meetings, and convened teaching sessions. This will continue to be demonstrated during the further analysis of the outcomes and dissemination of the findings.

3. DNP Essential III. Clinical Scholarship and Analytical Methods for Evidence-Based Practice

This DNP essential was demonstrated during participation in each stage of the project: developing the DNP project proposal, preparing the manuscript, planning for the project, attending project team meetings, and conducting ongoing assessments and evaluations. This was also demonstrated during data collection, data analysis, and consultation with members of the team and the statistician.

4. DNP Essential IV. Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Healthcare

This DNP essential was demonstrated when data extraction of poor HbA1c levels from the large data set (Athenahealth dashboard) was done, which helped develop a plan for improving outcomes in diabetes for the institution, and helped create the project.

5. DNP Essential V. Interprofessional Collaboration for Improving Patient and Population Health Outcomes

This DNP essential was demonstrated while collaborating with the interprofessional team: the behavioral health department, pharmacy department, family medicine department, etc., and also during the consultation with the mentor who is also the medical director, by email, zoom meetings, phone, and in-person visits.

6. DNP Essential VI. Advance Nursing Practice

This DNP essential was demonstrated when the organization was assessed in the practice setting, and when the project was devised and conducted. This essential was also demonstrated during the dissemination of the project results, and knowledge derivation with implications to the healthcare team.

Recommendations for Practice

In the clinic, the project was successfully implemented. Interdisciplinary collaboration was effectively utilized for the success of the project. The AGREE II tool, the checklist which helps to assess the quality of evidence-based guidelines, was used to evaluate the current project guideline. Issues brought up were: The views and preferences of the target patient population were not identified for this project. This would be included in a second or third iteration of the protocol since this is the first time “testing” the protocol in this practice setting. The body of evidence for this project was derived from a selective review, and this is a limiting factor.

Though it includes high levels of research evidence with a discussion of critical appraisal, an exhaustive review would provide stronger evidence. An engaged interprofessional team worked together to carry out the protocol. Stable team membership with stronger team involvement is strongly recommended for consideration during the next steps in the process (PDSA).

Recommendations for future revisions will be addressed after the first PDSA cycle. The process flow map made the recommendations clear. Attempts were made to standardize the CBT content so that it was clear about what “happens” in the CBT related to specific diabetes distress items and how this might impact patients. Further attempts will be made to streamline and standardize it further which will provide greater clarity. The post-CBT questions helped shed light on patients’ perceptions and helped make their voices heard. There was no funding agency, hence

there was no undue external influence. The guidelines would undergo further testing in the next successive cycles. We will continue to update the guideline, using the AGREE II tool.

Overall Project Summary

Texas has the largest number of low-income uninsured patients, of which the majority are diabetic. Diabetes distress, which can result from poorly controlled diabetes, causes a vicious circle and results in poor patient outcomes. To tackle the issue of poor outcomes in T2DM, it is important to have multifaceted patient-centered interventions in place. An awareness and examination of the factors causing the issue, the nature and context of the issue, resources available, organizational climate, economic factors, etc., are especially important to devise optimal interventions for addressing the issue. Patient-centered interventions with proven benefits include the use of interventions like the CBT which was administered in the current project to optimize outcomes. Follow up call was done after two weeks from the CBT visits to capture the patients' voices and perceptions. Thematic analysis was done on the compiled qualitative data and there were several themes and patterns identified from the follow-up calls with the patients which showed that the intervention was beneficial for the patients.

Next Steps

Dissemination of findings from this scholarly project will occur in several different ways. It will be presented as a PowerPoint presentation to the students, DNP project team, and faculty at Texas Woman's University. Another presentation will be done at a meeting at the practice site where the data will be presented to stakeholders and staff. The manuscript will also be uploaded into the DNP repository, where it can be accessed by nurses and the public alike.

References

- Aguayo-Mazzucato, C., Diaque, P., Hernandez, S., Rosas, S., Kostic, A., & Caballero, A. E. (2019). Understanding the growing epidemic of type 2 diabetes in the Hispanic population living in the United States. *Diabetes/metabolism research and reviews*, 35(2), e3097. <https://doi.org/10.1002/dmrr.3097>
- Aikens, J. E. (2012). Prospective associations between emotional distress and poor outcomes in type 2 diabetes. *Diabetes care*, 35(12), 2472-2478. <https://doi.org/10.2337/dc12-0181>
- Alanzi T, Alanazi NR, Istepanian R, Philip N. Evaluation of the effectiveness of mobile diabetes management system with social networking and cognitive behavioral therapy (CBT) for T2D. *Mhealth* (2018) 4:35. doi: 10.21037/mhealth.2018.06.05
- American Association of Colleges of Nursing. (2021). The Essentials: Core Competencies for Professional Nursing Education. Retrieved from: <https://www.aacnnursing.org/About-AACN/AACN-Governance/Committees-and-Task-Forces/Essentials>
- American Diabetes Association. (2018). Economic costs of diabetes in the US in 2017. *Diabetes care*, 41(5), 917-928. <https://doi.org/10.2337/dci18-0007>
- American Diabetes Association. (2020). Glycemic Targets: Standards of Medical Care in Diabetes-2020. *Diabetes Care*, 43(Suppl 1), S66. <https://doi.org/10.2337/dc20-S006>
- American Diabetes Association. (2020). Standards of Medical Care in Diabetes—2020 abridged for primary care providers. *Clinical Diabetes*, 38(1), 10-38. <https://doi.org/10.2337/cd20-as01>

- American Psychological Association. (2015). Society of Clinical Psychology. Therapy for depression in diabetes. Retrieved from Cognitive-Behavioral Therapy for Depression in People with Diabetes | Society of Clinical Psychology (div12.org)
- America's Health Rankings analysis of America's Health Rankings composite measure, United Health Foundation, State Summaries Texas | 2020 Annual Report | AHR (americashealthrankings.org) Accessed 2021.
- Andreae, S. J., Andreae, L. J., Richman, J. S., Cherrington, A. L., & Safford, M. M. (2020). Peer-delivered cognitive behavioral training to improve functioning in patients with diabetes: a cluster-randomized trial. *The Annals of Family Medicine*, 18(1), 15-23. DOI: <https://doi.org/10.1370/afm.2469>
- Aqtam, I., & Darawwad, M. (2018). Health promotion model: An integrative literature review. *Open Journal of Nursing*, 8(07), 485. <https://doi.org/10.4236/ojn.2018.87037>
- Barnes, J. A., Eid, M. A., Creager, M. A., & Goodney, P. P. (2020). Epidemiology and risk of amputation in patients with diabetes mellitus and peripheral artery disease. *Arteriosclerosis, Thrombosis, and Vascular Biology*, 40(8), 1808-1817. <https://doi.org/10.1161/ATVBAHA.120.314595>
- Beléndez, M., Hernández-Mijares, A., Marco, J., Domínguez, J. R., & Pomares, F. J. (2014). Validation of the Spanish version of the Problem Areas in Diabetes (PAID-SP) Scale. *Diabetes research and clinical practice*, 106(3), e93-e95. <https://doi.org/10.1016/j.diabres.2014.09.012>
- Bermúdez-Millán, A., Pérez-Escamilla, R., Segura-Pérez, S., Damio, G., Chhabra, J., Osborn, C. Y., & Wagner, J. (2016). Psychological distress mediates the association between food insecurity and suboptimal sleep quality in Latinos with type 2 diabetes mellitus. *The*

- Journal of nutrition*, 146(10), 2051-2057. <https://doi.org/10.3945/jn.116.231365>
- Berry, E., Lockhart, S., Davies, M., Lindsay, J. R., & Dempster, M. (2015). Diabetes distress: understanding the hidden struggles of living with diabetes and exploring intervention strategies. *Postgraduate medical journal*, 91(1075), 278-283.
<http://dx.doi.org/10.1136/postgradmedj-2014-133017>
- Braun, V., Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3, 77–101. doi:10.1191/1478088706qp063oa
- Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report (2020). Retrieved from
https://www.cdc.gov/diabetes/data/statistics/statistics-report.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fdiabetes%2Fdata%2Fstatistics-report%2Fdiagnosed.html
1
- Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2019 on CDC WONDER Online Database, released in 2020. Data from the Multiple Cause of Death Files, 1999-2019, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.
Accessed at <http://wonder.cdc.gov/ucd-icd10.html> on 06/06/2021
- Centers for Disease Control and Prevention Wonder Data (CDC Wonder). Retrieved from Underlying Cause of Death, 2018-2019, Single Race Results Form (cdc.gov)
- Cummings, D. M., Lutes, L. D., Littlewood, K., Solar, C., Carraway, M., Kirian, K., ... & Hambidge, B. (2019). Randomized trial of a tailored cognitive behavioral intervention in type 2 diabetes with comorbid depressive and/or regimen-related distress symptoms: 12-month outcomes from COMRADE. *Diabetes Care*, 42(5), 841-848.

<https://doi.org/10.2337/dc18-1841>

- Das, S. R., Everett, B. M., Birtcher, K. K., Brown, J. M., Januzzi Jr, J. L., Kalyani, R. R., ... & Sperling, L. S. (2020). 2020 expert consensus decision pathway on novel therapies for cardiovascular risk reduction in patients with type 2 diabetes: a report of the American College of Cardiology solution set oversight committee. *Journal of the American College of Cardiology*, 76(9), 1117-1145. <https://doi.org/10.1016/j.jacc.2020.05.037>
- De Boer, I. H., Bangalore, S., Benetos, A., Davis, A. M., Michos, E. D., Muntner, P., ... & Bakris, G. (2017). Diabetes and hypertension: a position statement by the American Diabetes Association. *Diabetes Care*, 40(9), 1273-1284. <https://doi.org/10.2337/dci17-0026>
- Dennick, K., Sturt, J., & Speight, J. (2017). What is diabetes distress and how can we measure it? A narrative review and conceptual model. *Journal of Diabetes and its Complications*, 31(5), 898-911. <https://doi.org/10.1016/j.jdiacomp.2016.12.018>
- Edmondson, D., Falzon, L., Sundquist, K. J., Julian, J., Meli, L., Sumner, J. A., & Kronish, I. M. (2018). A systematic review of the inclusion of mechanisms of action in NIH-funded intervention trials to improve medication adherence. *Behaviour Research and Therapy*, 101, 12–19. <https://doi.org/10.1016/j.brat.2017.10.001>
- Fisher, L., Polonsky, W. H., & Hessler, D. (2019). Addressing diabetes distress in clinical care: a practical guide. *Diabetic Medicine*, 36(7), 803-812. <https://doi.org/10.1111/dme.13967>
- Fisher, L., Mullan, J. T., Arean, P., Glasgow, R. E., Hessler, D., & Masharani, U. (2010). Diabetes distress but not clinical depression or depressive symptoms is associated with glycemic control in both cross-sectional and longitudinal analyses. *Diabetes care*, 33(1), 23-28. <https://doi.org/10.2337/dc09-1238>

- Franco, P., Gallardo, A. M., & Urtubey, X. (2018). Web-based interventions for depression in individuals with diabetes: review and discussion. *JMIR Diabetes*, 3(3), e13. doi: 10.2196/diabetes.9694
- Hermanns, N., Schmitt, A., Gahr, A., Herder, C., Nowotny, B., Roden, M., ... & Kulzer, B. (2015). The effect of a diabetes-specific cognitive behavioral treatment program (DIAMOS) for patients with diabetes and subclinical depression: results of a randomized controlled trial. *Diabetes Care*, 38(4), 551-560. <https://doi.org/10.2337/dc14-1416>
- Hessler, D., Fisher, L., Glasgow, R. E., Strycker, L. A., Dickinson, L. M., Arean, P. A., & Masharani, U. (2014). Reductions in regimen distress are associated with improved management and glycemic control over time. *Diabetes Care*, 37(3), 617-624. <https://doi.org/10.2337/dc13-0762>
- Huang, C. Y., Lai, H. L., Chen, C. I., Lu, Y. C., Li, S. C., Wang, L. W., & Su, Y. (2016). Effects of motivational enhancement therapy plus cognitive behavior therapy on depressive symptoms and health-related quality of life in adults with type II diabetes mellitus: a randomized controlled trial. *Quality of Life Research*, 25(5), 1275-1283. <https://doi.org/10.1007/s11136-015-1165-6>
- Institute for Healthcare Improvement (IHI). IHI Triple Aim Initiative. <http://www.ihl.org/engage/initiatives/TripleAim/Pages/default.aspx>.
- Jackson, J. L., & Kroenke, K. (2001). The effect of unmet expectations among adults presenting with physical symptoms. *Annals of internal medicine*, 134(9), 889-897. https://doi.org/10.7326/0003-4819-134-9_Part_2-200105011-00013
- Keisler Starkey K., & Bunch, L. N. (2020). Health insurance coverage in the United States: 2019. U.S. Census Bureau. *Current population reports. Washington DC: US Government*

Publishing Office.

Kleinsinger, F. (2018). The unmet challenge of medication nonadherence. *The Permanente Journal*, 22. doi: 10.7812/TPP/18-033

Koye, D. N., Magliano, D. J., Nelson, R. G., & Pavkov, M. E. (2018). The global epidemiology of diabetes and kidney disease. *Advances in chronic kidney disease*, 25(2), 121-132.
<https://doi.org/10.1053/j.ackd.2017.10.011>

Kreider, K. E. (2017). Diabetes distress or major depressive disorder? A practical approach to diagnosing and treating psychological comorbidities of diabetes. *Diabetes Therapy*, 8(1), 1-7. DOI 10.1007/s13300-017-0231-1

Lee, J., Lee, E. H., Kim, C. J., & Moon, S. H. (2015). Diabetes-related emotional distress instruments: a systematic review of measurement properties. *International journal of nursing studies*, 52(12), 1868-1878. <https://doi.org/10.1016/j.ijnurstu.2015.07.004>

Leyva, B., Zagarins, S. E., Allen, N. A., & Welch, G. (2011). The relative impact of diabetes distress vs depression on glycemic control in Hispanic patients following a diabetes self-management education intervention. *Ethnicity & disease*, 21(3), 322-327.

Li, S. A., Jeffs, L., Barwick, M., & Stevens, B. (2018). Organizational contextual features that influence the implementation of evidence-based practices across healthcare settings: a systematic integrative review. *Systematic reviews*, 7(1), 72. DOI
<https://doi.org/10.1186/s13643-018-0734-5>

Lukens, E. P., & McFarlane, W. R. (2004). Psychoeducation as Evidence-Based Practice: Considerations for Practice, Research, and Policy. *Brief Treatment & Crisis Intervention*, 4(3). DOI: 10.1093/brief-treatment/mhh019

Mathiesen, A. S., Egerod, I., Jensen, T., Kaldan, G., Langberg, H., & Thomsen, T. (2019).

- Psychosocial interventions for reducing diabetes distress in vulnerable people with type 2 diabetes mellitus: a systematic review and meta-analysis. *Diabetes, metabolic syndrome and obesity: targets and therapy*, 12, 19. doi: 10.2147/DMSO.S179301
- McGuire, B. E., Morrison, T. G., Hermanns, N., Skovlund, S., Eldrup, E., Gagliardino, J., ... & De Wit, M. (2010). Short-form measures of diabetes-related emotional distress: The Problem Areas in Diabetes Scale (PAID)-5 and PAID-1. *Diabetologia*, 53(1), 66.
<https://doi.org/10.1007/s00125-009-1559-5>
- Mind Tools. (n.d.). *SWOT analysis: How to develop a strategy for success*.
https://www.mindtools.com/pages/article/newTMC_05.htm
- Moulton, C. D., Pickup, J. C., & Ismail, K. (2015). The link between depression and diabetes: the search for shared mechanisms. *The Lancet Diabetes & Endocrinology*, 3(6), 461-471.
[https://doi.org/10.1016/S2213-8587\(15\)00134-5](https://doi.org/10.1016/S2213-8587(15)00134-5)
- Naranjo, C., Ortega-Jiménez, P., Del Reguero, L., Moratalla, G., & Failde, I. (2020). Relationship between diabetic neuropathic pain and comorbidity. Their impact on pain intensity, diabetes complications, and quality of life in patients with type-2 diabetes mellitus. *Diabetes research and clinical practice*, 165, 108236.
<https://doi.org/10.1016/j.diabres.2020.108236>
- Newby, J., Robins, L., Wilhelm, K., Smith, J., Fletcher, T., Gillis, I., ... & Andrews, G. (2017). Web-based cognitive behavior therapy for depression in people with diabetes mellitus: a randomized controlled trial. *Journal of medical Internet research*, 19(5), e157. doi: 10.2196/jmir.7274
- Ni, Y., Ma, L., & Li, J. (2020). Effects of Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy in People with Diabetes: A Systematic Review

- and Meta-Analysis. *Journal of Nursing Scholarship*. <https://doi.org/10.1111/jnu.12560>
- Noroozi, Z., Hamidian, S., Khajeddin, N., Honarmand, M. M. Z., Zargar, Y., Rashidi, H., & Dolatshahi, B. (2017). Improving depression, and quality of life in patients with type 2 diabetes: using group cognitive behavior therapy. *Iranian journal of psychiatry*, 12(4), 281. PMCID: PMC5816918.
- Pandit, A. U., Bailey, S. C., Curtis, L. M., Seligman, H. K., Davis, T. C., Parker, R. M., ... & Wolf, M. S. (2014). Disease-related distress, self-care and clinical outcomes among low-income patients with diabetes. *J Epidemiol Community Health*, 68(6), 557-564. <http://dx.doi.org/10.1136/jech-2013-203063>
- Pender, N. J. (2011). Health promotion model manual. <http://hdl.handle.net/2027.42/85350>
- Petrak F, Herpertz S, Albus C, Hermanns N, Hiemke C, Hiller W, et al. Cognitive behavioral therapy versus sertraline in patients with depression and poorly controlled diabetes: The Diabetes and Depression (DAD) Study: A randomized controlled multicenter trial. *Diabetes Care* (2015) 38(5):767–75. doi: 10.2337/dc14-1599
- Perrin, N., Bodicoat, D. H., Davies, M. J., Robertson, N., Snoek, F. J., & Khunti, K. (2019). Effectiveness of psychoeducational interventions for the treatment of diabetes-specific emotional distress and glycaemic control in people with type 2 diabetes: a systematic review and meta-analysis. *Primary care diabetes*, 13(6), 556-567. <https://doi.org/10.1016/j.pcd.2019.04.001>
- Perrin, N. E., Davies, M. J., Robertson, N., Snoek, F. J., & Khunti, K. (2017). The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. *Diabetic Medicine*, 34(11), 1508-1520. <https://doi.org/10.1111/dme.13448>

- Pop-Busui, R., Boulton, A. J., Feldman, E. L., Bril, V., Freeman, R., Malik, R. A., ... & Ziegler, D. (2017). Diabetic neuropathy: a position statement by the American Diabetes Association. *Diabetes care*, 40(1), 136-154. <https://doi.org/10.2337/dc16-2042>
- Pouwer, F., Schram, M. T., Iversen, M. M., Nouwen, A., & Holt, R. I. G. (2020). How 25 years of psychosocial research has contributed to a better understanding of the links between depression and diabetes. *Diabetic Medicine*, 37(3), 383-392. <https://doi.org/10.1111/dme.14227>
- Rao, J. K., Weinberger, M., & Kroenke, K. (2000). Visit-specific expectations and patient-centered outcomes: a literature review. *Archives of Family Medicine*, 9(10), 1148. DOI: 10.1001/archfami.9.10.1148
- Rariden, C. (2019). Diabetes Distress: Assessment and Management of The Emotional Aspect of Diabetes Mellitus. *The Journal for Nurse Practitioners*, 15(9), 653-656. <https://doi.org/10.1016/j.nurpra.2019.06.020>
- Rustveld, L. O., Pavlik, V. N., Jibaja-Weiss, M. L., Kline, K. N., Gossey, J. T., & Volk, R. J. (2009). Adherence to diabetes self-care behaviors in English-and Spanish-speaking Hispanic men. *Patient preference and adherence*, 3, 123.doi: 10.2147/ppa.s5383
- San Jose Clinic. Mission Statement. Retrieved from <https://www.sanjoseclinic.org/history>
- Schmidt, C. B., van Loon, B. P., Vergouwen, A. C. M., Snoek, F. J., & Honig, A. (2018). Systematic review and meta-analysis of psychological interventions in people with diabetes and elevated diabetes distress. *Diabetic Medicine*, 35(9), 1157-1172. <https://doi.org/10.1111/dme.13709>
- Schmitt, A., Reimer, A., Kulzer, B., Haak, T., Ehrmann, D., & Hermanns, N. (2016). How to assess diabetes distress: comparison of the Problem Areas in Diabetes Scale (PAID) and

- the Diabetes Distress Scale (DDS). *Diabetic Medicine*, 33(6), 835-843.
<https://doi.org/10.1111/dme.12887>
- Schroevers, M. J., Tovote, K. A., Keers, J. C., Links, T. P., Sanderman, R., & Fleer, J. (2015). Individual mindfulness-based cognitive therapy for people with diabetes: A pilot randomized controlled trial. *Mindfulness*, 6(1), 99-110.
<https://doi.org/10.1007/s12671-013-0235-5>
- Skinner, T. C., Joensen, L., & Parkin, T. (2020). Twenty-five years of diabetes distress research. *Diabetic Medicine*, 37(3), 393-400. <https://doi.org/10.1111/dme.14157>
- Solomon, S. D., Chew, E., Duh, E. J., Sobrin, L., Sun, J. K., VanderBeek, B. L., ... & Gardner, T. W. (2017). Diabetic retinopathy: a position statement by the American Diabetes Association. *Diabetes care*, 40(3), 412-418. <https://doi.org/10.2337/dc16-2641>
- Uchendu, C., & Blake, H. (2017). Effectiveness of cognitive-behavioral therapy on glycemic control and psychological outcomes in adults with diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials. *Diabetic Medicine*, 34(3), 328-339.
<https://doi.org/10.1111/dme.13195>
- Wardian, J. L., Kanzler, K. E., True, M. W., Glotfelter, M. A., & Sauerwein, T. J. (2019). Is It Distress, Depression, or Both? Exploring Differences in the Diabetes Distress Scale and the Patient Health Questionnaire in a Diabetes Specialty Clinic. *Clinical Diabetes*, 37(2), 124-130. <https://doi.org/10.2337/cd18-0047>
- Welch, G., Schwartz, C. E., Santiago-Kelly, P., Garb, J., Shayne, R., & Bode, R. (2007). Disease-related emotional distress of Hispanic and non-Hispanic type 2 diabetes patients. *Ethnicity & disease*, 17(3), 541-547. <https://doi.org/10.2337/cd18-0047>
- Whitehead, L. C., Crowe, M. T., Carter, J. D., Maskill, V. R., Carlyle, D., Bugge, C., &

- Frampton, C. M. (2017). A nurse-led education and cognitive behavior therapy-based intervention among adults with uncontrolled type 2 diabetes: A randomized controlled trial. *Journal of evaluation in clinical practice*, 23(4), 821-829.
<https://doi.org/10.1111/jep.12725>
- Wroe AL, Rennie EW, Sollesse S, Chapman J, Hassy A. (2018). Is Cognitive Behavioral Therapy focusing on Depression and Anxiety Effective for People with Long-Term Physical Health Conditions? A Controlled Trial in the Context of Type 2 Diabetes Mellitus. *Behavioral and Cognitive Psychotherapy*, 46(2):129–47. doi: 10.1017/S1352465817000492
- Yang, X., Li, Z., & Sun, J. (2020). Effects of Cognitive Behavioral Therapy–Based Intervention on Improving Glycemic, Psychological, and Physiological Outcomes in Adult Patients with Diabetes Mellitus: A Meta-Analysis of Randomized Controlled Trials. *Frontiers in psychiatry*, 11, 711. <https://doi.org/10.3389/fpsyt.2020.00711>
- Young-Hyman, D., De Groot, M., Hill-Briggs, F., Gonzalez, J. S., Hood, K., & Peyrot, M. (2016). Psychosocial care for people with diabetes: a position statement of the American Diabetes Association. *Diabetes care*, 39(12), 2126-2140.
<https://doi.org/10.2337/dc16-2053>

Appendix A: The Measure of Interest / Metric Needed

Measure of interest	Measure Metric needed	Type of Measure	Period for Measure	Operational Definition-Denominator	Operational Definition-Numerator	Data elements needed to operationalize the measure	Level of Measure needed for data	Location of Data	Data owner/ Requires Permission of use?
PAID instrument screenings being done-pre-intervention	Number of patients who completed the screen	Process	Once Pre CBT visit	Number of days	Number of screenings done	Number of screens and number of days	Count-Need ratio level data	Data are available in Electronic hospital record (EHR) Athena-health	Data is owned by the clinic. No permission is needed.
Number of CBT sessions being done	Number of patients who completed the CBT session	Process	Weekly	Number of days	Number of CBT sessions done	Number of CBT sessions and number of days	Count-Need ratio level data	Data are available in Electronic hospital record (EHR) Athena-health	Data is owned by the clinic. No permission is needed.
PAID instrument screenings being done-post-intervention	Number of patients who completed the screen	Outcome	Once. Post- CBT	Number of days	Number of screenings done	Number of screens and number of days	Count-Need ratio level data	Data are available in Electronic hospital record (EHR) Athena-health	Data is owned by the clinic. No permission is needed.
HbA1C	glycemic control	Outcome	Once in the previous year from visit, and the next visit after CBT	Number of tests done	Number of tests done	Value/ result	Interval	Data are available in Electronic hospital record (EHR) Athena-health	Data is owned by the clinic. No permission needed
Fasting blood sugar	glycemic control	Outcome	Latest data from visit-pre and post	Number of tests done	Number of tests done	Value/ result	Interval	Data are available in Electronic hospital record (EHR) Athena-health	Data is owned by the clinic. No permission needed

Appendix B: Evidence Table

Author and Date	Theoretical Conceptual Framework	Research Question/ Hypothesis	Methodology	Analysis and Results	Level of Evidence	Critical Appraisal
1. The Effect of a Diabetes-Specific Cognitive Behavioral Treatment Program (DIAMOS) for Patients with Diabetes and Subclinical Depression: Results of a Randomized Controlled Trial (Hermanns, 2015).	None identified	Evaluation of the CBT intervention: self-management-oriented group program: Diabetes Motivation Strengthening (DIAMOS)- composed of cognitive behavioral interventions aiming at the reduction of diabetes distress.	The control group received diabetes education. The primary outcome was depressive symptoms. Secondary outcomes included diabetes distress and HbA1c.	After a 12-month follow-up, the reduction of depressive symptoms was significant in the DIAMOS group compared to the control group. The PAID questionnaire, PHQ9, and Diabetes distress scales were found to be effective.	Level 1 RCT	CBT was found more effective in lowering depressive symptoms and diabetes distress in diabetic patients with subclinical depression. It also reduced the incidence of major depression.

2. Cognitive Behavioral Therapy Versus Sertraline in Patients with Depression and Poorly Controlled Diabetes: The Diabetes and Depression (DAD) Study (Petrak et al., 2015).	None identified	To compare the long-term efficacy of a diabetes-specific CBT with sertraline in patients having diabetes and depression who initially responded to short-term depression treatment.	The trial was conducted in 70 secondary care centers across Germany comparing 12 weeks of CBT with sertraline in 251 patients with poorly controlled diabetes (type 1 or 2) and depression.	Adjusted HbA1c mean score changes from baseline to the end of the long-term phase revealed no significant difference between the interventions. Depression improved in both groups.	Level 1 RCT	Depression improved under CBT and sertraline in patients with diabetes and depression, but the change in glycemic control was not significant. CBT and sertraline were recommended to be used together for diabetic patients with depression and poor glycemic control.
--	-----------------	---	---	---	-------------	---

3. Effects of motivational enhancement therapy plus cognitive behavior therapy on depressive symptoms and health-related quality of life in adults with type II diabetes mellitus: a randomized controlled trial (Huang et al., 2016).	None identified	To compare patients who received the behavioral intervention with controls who did not receive it, on measures of health outcomes	A total of 31 intervention group participants and 30 controls were selected from patients meeting the inclusion criteria from a hospital-based endocrinology outpatient department.	The experimental group showed a significant reduction in HbA1c, fasting glucose, and depressive symptoms and a significant increase in physical and mental quality of life. The patients in the control group with usual care showed no changes.	Level 1 RCT	The behavioral intervention resulted in a significant improvement in psychological adjustment and glycemic control. This strengthened diabetes control skills and led to healthy outcomes.
--	-----------------	---	---	--	-------------	--

4. Web-Based Cognitive Behavior Therapy for Depression in People with Diabetes Mellitus: A Randomized Controlled Trial (Newby et al., 2017).	None identified	To examine the effectiveness of a 6-lesson iCBT delivered over 10 weeks in people with major depressive disorder and diabetes.	Participants were randomized to an iCBT program where therapist support was provided by phone and email (n=42) or a control group with treatment as usual (n=49). Primary outcomes included diabetes-relat ed distress (PAID) and glycemic control (HbA1c).	27 participants completed the iCBT program. The iCBT was found superior over TAU at post-treatment on instrument scores, but there were no significant differences in HbA1c levels.	Level 1 RCT	iCBT was useful for reducing diabetes distress. Future studies should explore the effect of tailored iCBT programs.
---	--------------------	--	--	---	----------------	---

5. A nurse-led education and cognitive behavior therapy-based intervention among adults with uncontrolled type 2 diabetes: A randomized controlled trial (Whitehead et al., 2017).	None identified	To determine whether a nurse-led educational intervention alone or a nurse-led intervention using education and acceptance and commitment therapy was effective in reducing HbA1c in people living with uncontrolled T2DM compared to usual care.	The participants were adults over the age of 18 years, with a diagnosis of T2DM and HbA1c outside of the recommended range for 1 or more years. 118 participants completed baseline data collection.	A significant reduction in HbA1c in the education intervention group was found. At 6 months, HbA1c was reduced in both intervention groups and increased in the control group.	Level 1 RCT	HbA1c was reduced in both intervention groups at 6 months, with a greater reduction noted in the nurse-led education intervention.
--	-----------------	---	--	--	-------------	--

6. Improving Depression, and Quality of Life in Patients with Type 2 Diabetes: Using Group Cognitive Behavior Therapy (Noorozi et al., 2017).	None identified	To investigate the effect of the group CBT technique on depression and quality of life in women with T2DM.	The clinical trial was conducted among 30 women with T2DM and comorbid depression. The intervention group received 10 sessions of group CBT while the control group did not.	The results showed that group CBT decreased depression symptoms and improved the quality of life of the patients in the intervention group compared to the control group.	Level 1 RCT	The results showed that group CBT can affect depression symptoms, and improve patients' quality of life.
---	-----------------	--	--	---	-------------	--

7. Evaluation of the effectiveness of mobile diabetes management system with social networking and cognitive behavioral therapy (CBT) for T2D (Alanzi et al., 2018).	None identified	To evaluate the application and utility of the SANAD system (Saudi Arabia Networking for Aiding Diabetes) to support adult T2DM patients in Saudi Arabia.	Twenty patients from a clinic in Saudi Arabia participated. The intervention group used the SANAD system and the control group used conventional diabetes treatment. HbA1c, diabetes knowledge test, and Self-efficacy Scale were documented.	Nineteen patients completed the study. Mean baseline HbA1c (%) was 8.14 and decreased to 7.54 after the SANAD intervention. A paired-samples <i>t</i> -test showed that the change was significant ($P=0.000$).	Level 1, RCT	This study showed that the use of the SANAD system was acceptable, and feasible for supporting diabetes care in Saudi Arabia.
--	-----------------	---	---	---	--------------	---

8. Is Cognitive Behavioral Therapy focusing on Depression and Anxiety Effective for People with Long-Term Physical Health Conditions? A Controlled Trial in the Context of Type 2 Diabetes Mellitus (Wroe et al., 2018).	None identified	To evaluate the effectiveness of a modified evidence-based psychological intervention which focuses on depression and anxiety for T2DM patients, compared with a control group.	Patients were allocated either to a diabetes-specific treatment or a standard intervention. Each condition received a group intervention offering evidence-based psychological interventions. The diabetes-specific treatment intervention helped patients to link mood with the management of T2DM.	Both conditions demonstrated improvements in the primary and the secondary outcomes. The diabetes-specific treatment condition also demonstrated improvements in secondary outcomes of self-report management of T2DM for diet, checking blood glucose, and checking feet, compared with the control.	Level 1 RCT	It was concluded that a modified intervention with specialist services input, offered additional benefits in terms of improved diabetic self-management and better glycemic control.
--	-----------------	---	--	---	-------------	--

9. Peer-Delivered Cognitive Behavioral Training to Improve Functioning in Patients with Diabetes: A Cluster-Randomized Trial (Andrea et al., 2020).	None identified	To test the effectiveness of a peer-delivered diabetes self-management program which integrated CBT principles for improving physical activity, functional status, pain, quality of life (QOL), and outcomes in diabetic patients.	Intervention participants received a 3-month, peer-delivered, telephone-administered program. The other participants received a peer-delivered general health advice program. Outcomes included changes in functional status, QOL, and physiologic measures.	Intervention participants had greater improvement in functional status. Physiologic measures did not change significantly in either group. The intervention improved functioning, pain, QOL, and self-reported physical activity.	Level 1, RCT	CBT-based interventions can be effective in rural and under-resourced communities, as delivered by trained community members, to improve outcomes.
--	-----------------	--	--	---	--------------	--

10. Individual Mindfulness- Based Cognitive Therapy for People with Diabetes: a Pilot Randomized Controlled Trial (Schroevers et al., 2015).	None identified	The feasibility of screening, recruiting, randomizing, and retaining patients into the study and their acceptability of I-MBCT	Descriptive analyses done exploring changes in patients' functioning, comparing those receiving I-MBCT with those in the control group. Patients completed self-report questionnaires pre-and post-interventi on.	Patients receiving I-MBCT reported significant reductions in depressive symptoms, diabetes distress, and improvements in 'act with awareness' and attention regulation compared to the control group.	Level 1 RCT	The I-MBCT resulted in improved psychological functioning and reduced depressive symptoms and diabetes distress.
---	--------------------	---	---	--	----------------	---

11. Effectiveness of cognitive-behavioral therapy on glycemic control and psychological outcomes in adults with diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials. (Uchendu et al., 2017).	None identified	To establish the effectiveness of CBT on glycemic control and diabetes distress, depression, anxiety, and quality of life in adults with diabetes (short, medium, and longer-term).	An electronic search was conducted and 12 RCTs were identified that evaluated the effectiveness of CBT on at least one of: glycemic control, diabetes distress, anxiety, depression, or quality of life.	CBT was effective in reducing short-term and medium-term glycemic control. There was no significant effect on long-term glycemic control. CBT improved short- and medium-term anxiety and depression, and long-term depression. Mixed results were found for diabetes distress and quality of life.	Systematic review and meta-analysis of RCTs.	CBT was found beneficial in improving depression for diabetic adults. It may benefit in improving glycemic control and other aspects of psychological health (the findings were inconclusive).
--	-----------------	---	--	---	--	--

12. Effects of Cognitive Behavioral Therapy–Based Intervention on Improving Glycemic, Psychological, and Physiological Outcomes in Adult Patients with Diabetes Mellitus: A Meta-Analysis of Randomized Controlled Trials (Yang et al., 2020).	None identified	To provide an overview of the effectiveness of CBT-based interventions for improving glycemic control, psychological, and physiological outcomes in adult diabetic patients.	The primary outcome variables included HbA1c, fasting plasma glucose, depression, and anxiety. Effect sizes were pooled by random-effects modelling using recommended Comprehensive Meta-Analysis software. The Physiotherapy Evidence Database tool was used to assess the quality of studies.	The results of the main analysis showed that CBT-based interventions had a better effect on reducing HbA1c and depression symptoms.	Meta-Analysis of RCTs	The results of the subgroup analysis suggested that it was necessary to adopt different types and technical components of CBT according to the population and purpose of the treatment. A further study including a large number of studies was recommended to confirm the results.
--	-----------------	--	---	---	-----------------------	---

13. Effectiveness of psychoeducational interventions for the treatment of diabetes-specific emotional distress and glycemic control in people with type 2 diabetes: a systematic review and meta-analysis (Perrin et al., 2019).	None identified	To determine interventions that successfully address diabetes distress and HbA1c in people with T2DM.	32 studies were selected from 7 databases and appraised independently by two reviewers. The data was synthesized; the primary analyses determined the effect of interventions on DSD, with secondary analyses assessing the effect on HbA1c.	Meta-analyses showed that interventions significantly reduced DSD and HbA1c compared to controls. But subgroup meta-analyses and meta-regression to find specific intervention characteristics mediating this effect yielded non-significant findings.	Systematic review and meta-analysis	Existing interventions successfully reduced DSD and HbA1c in people with T2DM. The researchers advised of the stark need for further focused exploration of how best to treat psychological comorbidity in people with T2DM.
---	-----------------	---	--	--	-------------------------------------	--

14. Systematic review and meta-analysis of psychological interventions in people with diabetes and elevated diabetes distress. Diabetic Medicine. (Schmidt et al., 2018).	None identified	To determine the efficacy of psychological interventions for treating diabetes distress in people with Type 1 or Type 2 diabetes.	Studies which described the results of psychological intervention in diabetic adults were included. The primary outcome was diabetes distress measured by the PAID scale or the Diabetes Distress Scale. The search yielded 8907 articles. After further selection there were 394 articles, nine of which were RCTs.	In a random-effects meta-analysis, the pooled effect size for diabetes-distress was 0.48 (Cohen's <i>d</i>). Diabetes-tailored psychological interventions reduced HbA1c whereas mindfulness-based interventions did not.	Systematic review and meta-analysis	Diabetes-tailored psychological interventions were found to be effective in reducing diabetes distress and HbA1c.
--	-----------------	---	--	--	-------------------------------------	---

15. Randomized trial of a tailored cognitive behavioral intervention in type 2 diabetes with comorbid depressive and/or regimen-related distress symptoms: 12-month outcomes from COMRADE (Cummings et al., 2019).	None identified	To evaluate the effect of CBT plus lifestyle counseling on HbA1c in rural adult patients with T2DM and comorbid depressive or regimen-related distress (RRD) symptoms.	139 diverse, rural adults with T2D and comorbid depressive or distress symptoms were included. Severity-tailored CBT plus lifestyle counseling intervention compared with usual care was done. Outcomes included changes in HbA1c, RRD, depressive symptoms, self-care behaviors, and medication adherence.	The intervention group had marginally significant improvements in HbA1c, but significantly greater improvements in RRD, depressive symptoms, and self-care behaviors. Improvement in HbA1c correlated with improvement in RRD and adherence.	Level 1 RCT	Tailored CBT with lifestyle counseling was found to improve behavioral outcomes and HbA1c in patients with T2DM and comorbid depressive and/or RRD symptoms.
---	-----------------	--	---	--	-------------	--

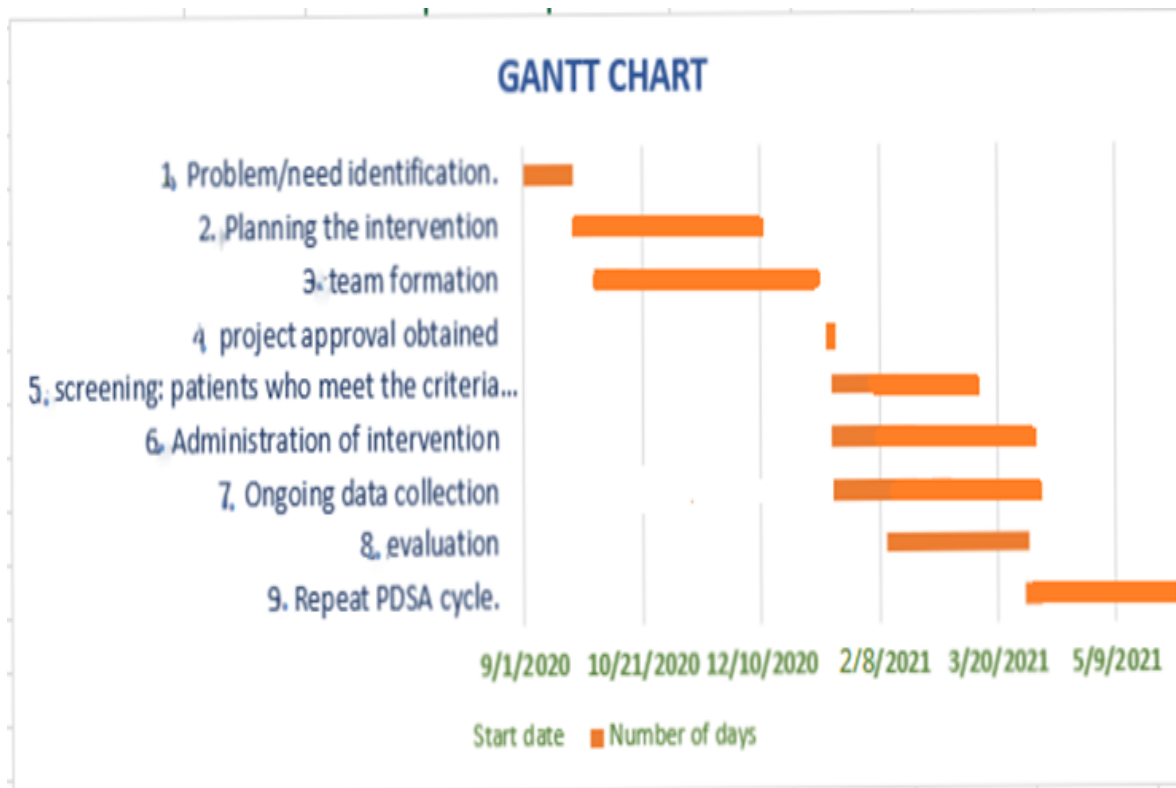
HbA1c: Glycated hemoglobin; DSD: Diabetes Specific Distress; T2DM: Type 2 Diabetes Mellitus; PAID-5: Problem Areas in Diabetes -5; RCT: Randomized Controlled Trial; RRD: Regimen related Distress; DRD: Diabetes-Related Distress.

Appendix C: SWOT Analysis

Table 1

SWOT Analysis for the QI Project

Strengths	Weaknesses
Support from the medical director, clinic manager, and administration	Difficulty in meeting with team members due to conflicting schedules
Engaged specialists from different services (behavioral health specialist, family medicine, pharmacist)	Staff being not clear of their role in improving patient engagement
Skilled clinical staff	Unfamiliarity with the interventions
Experienced members of the team in dealing with improving medication adherence	Patients with multiple comorbidities, different needs, and preferences
Access to database and availability of time	Patients with transportation issues
Opportunities	Threats
Advantage of increasing patient safety	COVID-19 causing direct and indirect impact.
Potential for reducing errors due to increased communication between staff and providers	COVID positive cases- resulting in appointment cancellations
Potential for increased patient satisfaction	Increase in stress in staff due to COVID
Potential for improving medication adherence	contacts and low staffing
	Staff who are resistant to change.
	Unanticipated costs (time/supplies)

Appendix D: GANTT CHART

Appendix E: PAID-5 Questionnaire

PAID-5

Instructions: Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
Feeling scared when you think about living with diabetes	0	1	2	3	4
Feeling depressed when you think about living with diabetes	0	1	2	3	4
Worrying about the future and the possibility of serious complications	0	1	2	3	4
Feeling that diabetes is taking up too much of your mental and physical energy every day	0	1	2	3	4
Coping with complications of diabetes	0	1	2	3	4

For the PAID-5, a total score of ≥ 8 indicates possible diabetes related emotional distress, which warrants further assessment. On the full 20-item PAID, a score of > 33 has been suggested as indicative of likely emotional distress and a score of 38 is indicative of possible depression and, in each case, further assessment is warranted. Further assessment is facilitated by reference to the specific items endorsed as problematic by the patient. Local service protocols can be developed whereby patients scoring above an agreed score, or those endorsing particular problems areas, should be referred to a mental health professional or specialist nurse for psychological support and treatment.

Appendix F: CBT Session Talking Points

Steps to Meaningful Clinician-Patient Conversation^a

Step	Conversation
Initiate dialog about distress	Know that we have reviewed your results, is this what you expected?
Identify and address feelings (frequently: humiliation, overwhelmed, sad, fault, irritation)	Describe how you are feeling about diabetes?
Recap and respond	How have you felt about...?
Normalization	To make sure I understand... Often patients share they feel this way... I can see why you feel that way... Other patients I have cared for with diabetes often feel...
Acknowledge resistance and reflect	On one hand you want to get better diabetes control, on the other hand you are frightened to increase the medication dose...
Add new insight	You feel you don't do anything right with your diabetes. While you struggle with one aspect, you do great at taking medication on time, keeping appointments, monitoring—so there are many things you are successful at...
Planning	How will you respond the next time you feel like you want to skip your medicine?

Rariden, C. (2019); Fisher et al., (2019).

Appendix G: Data Collection Form

DNP Program

Scholarly Project Data Collection Form [1 form per project participant]

Basic Data

Data Collector Name: _____
 Participant Name: _____
 Participant Number: _____
 Participant Gender: _____
 Participant Race: _____
 Participant Age: _____
 Participant Marital Status: _____
 Participant Educational Level: _____
 Participant Living Arrangement: _____
 Cognitive Behavioral Therapy Date Started: _____
 Cognitive Behavioral Therapy Date Ended: _____

Demographic Data [Other]

Variable	Value 1	Date 1	Value 2	Date 2	Value 3	Data 3	Other
Duration of Diabetes							
Medications Oral							
Medications Other							

Clinical Data

Variable	Value 1	Date 1	Value 2	Date 2	Value 3	Data 3	Other
PAID-5 pre							
PAID-5 post							
HbA1C pre							
HBA1C post							
Fasting blood sugar pre							
Fasting blood sugar post							

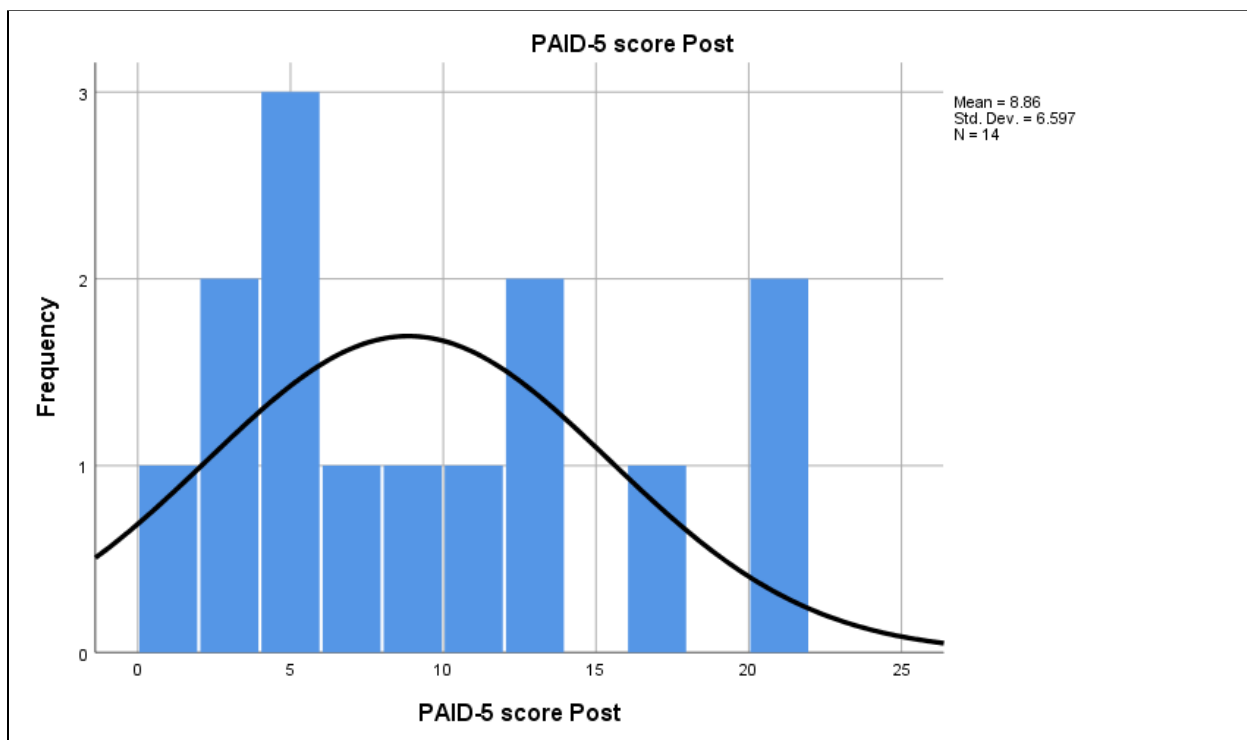
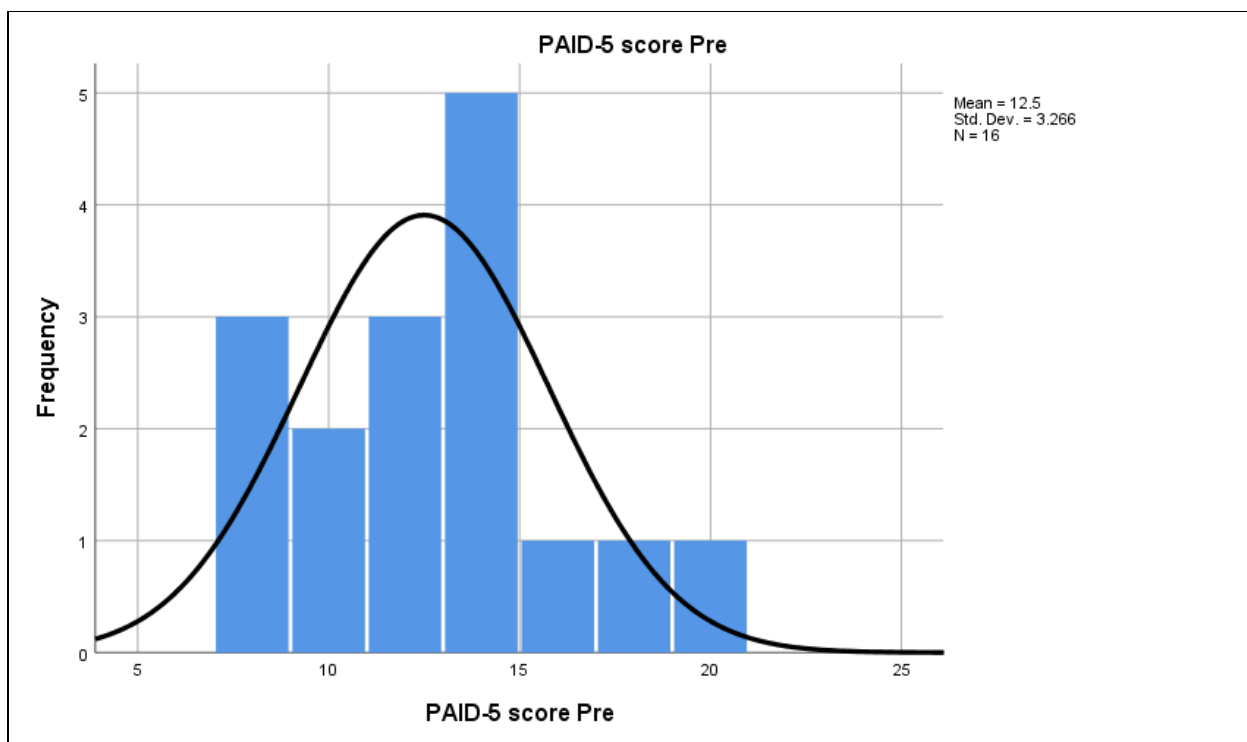
Other Data

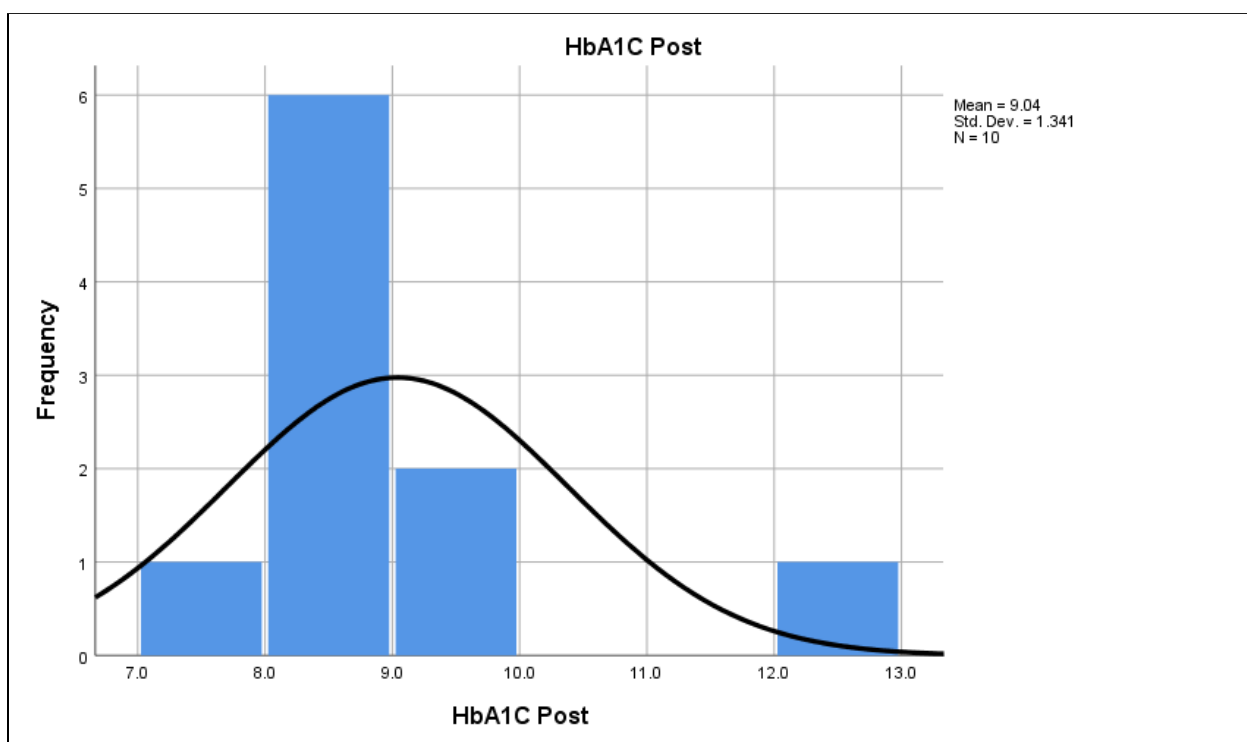
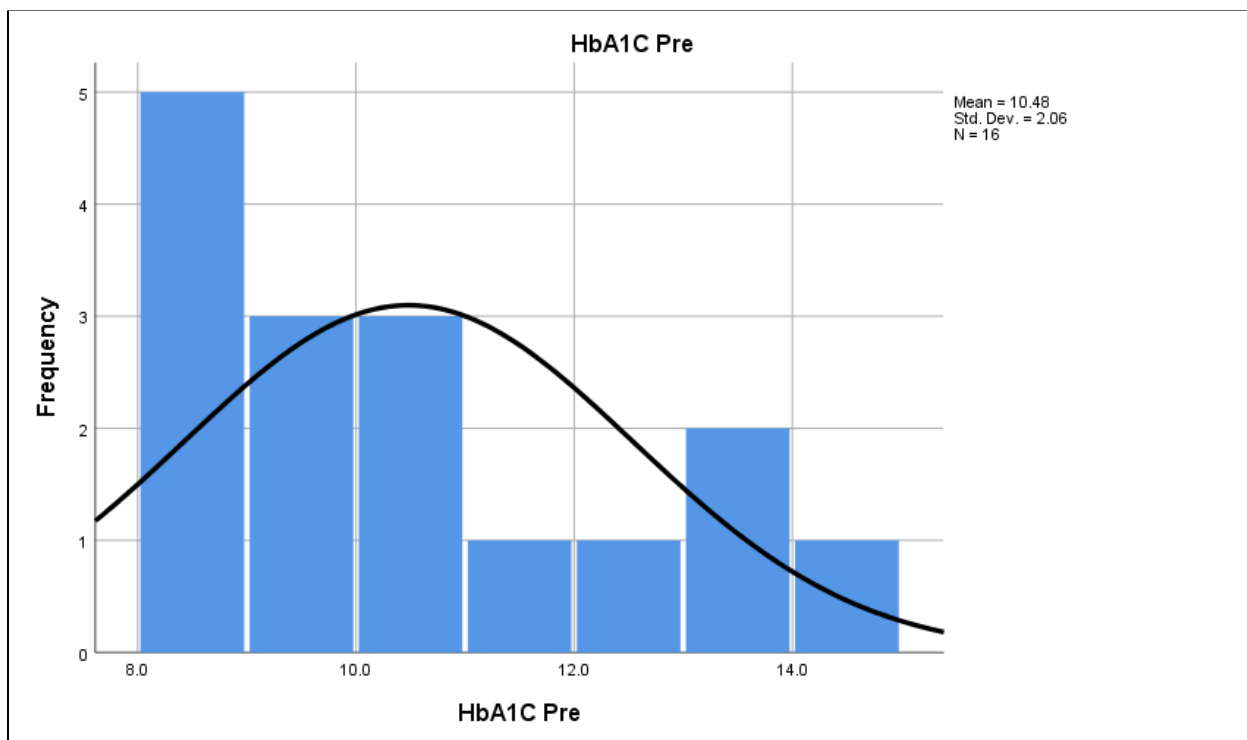
Open-ended Questions [2-Week Follow-up]:

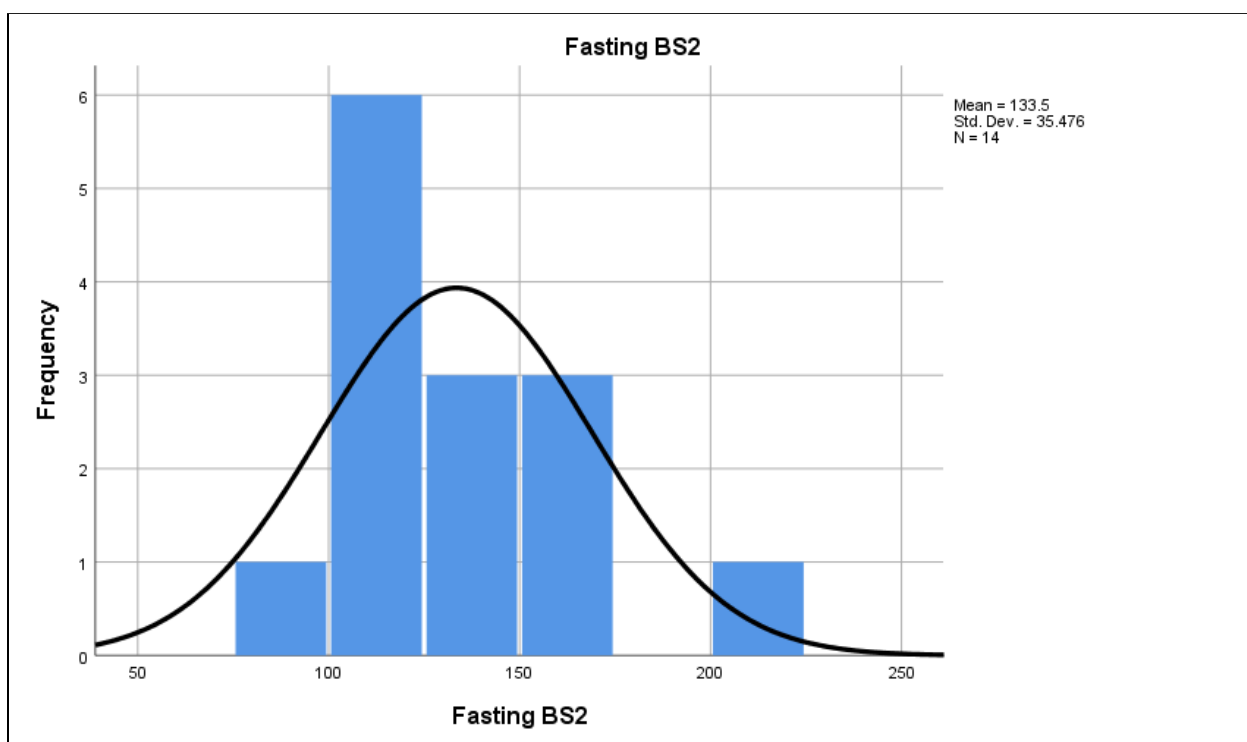
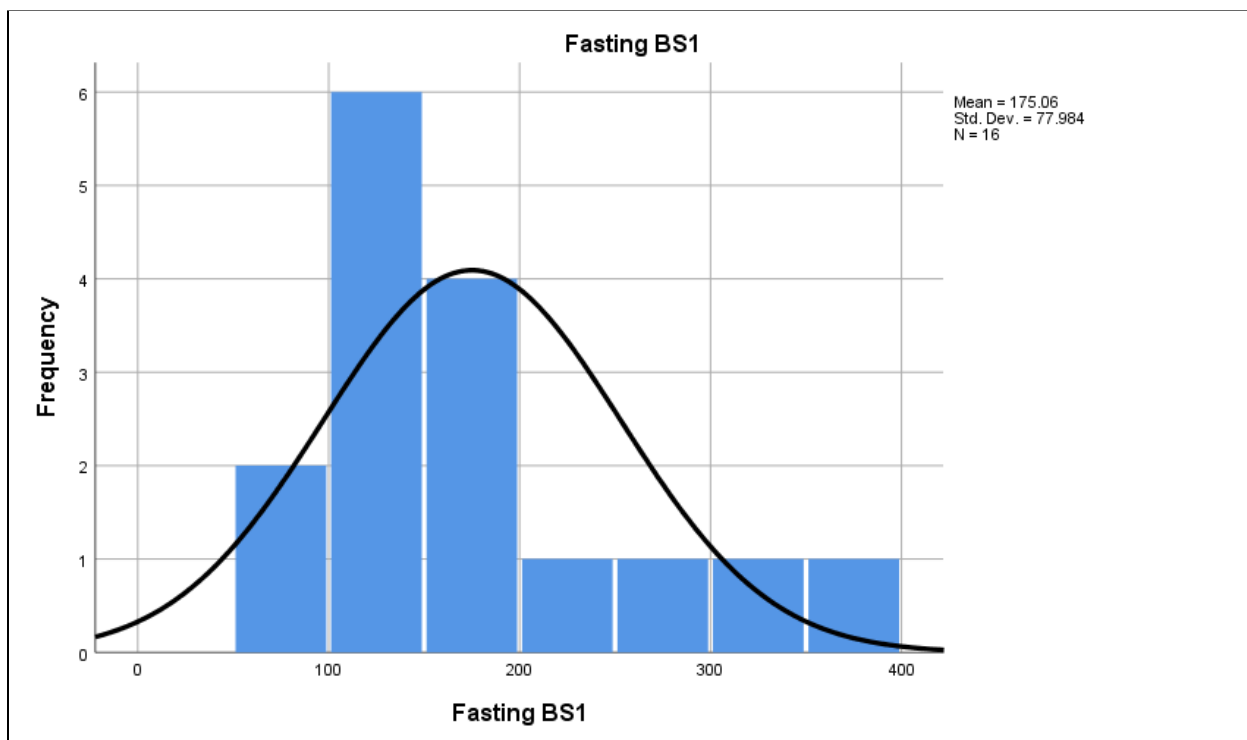
1. How was your experience with the Cognitive Behavioral Therapy (CBT) session?

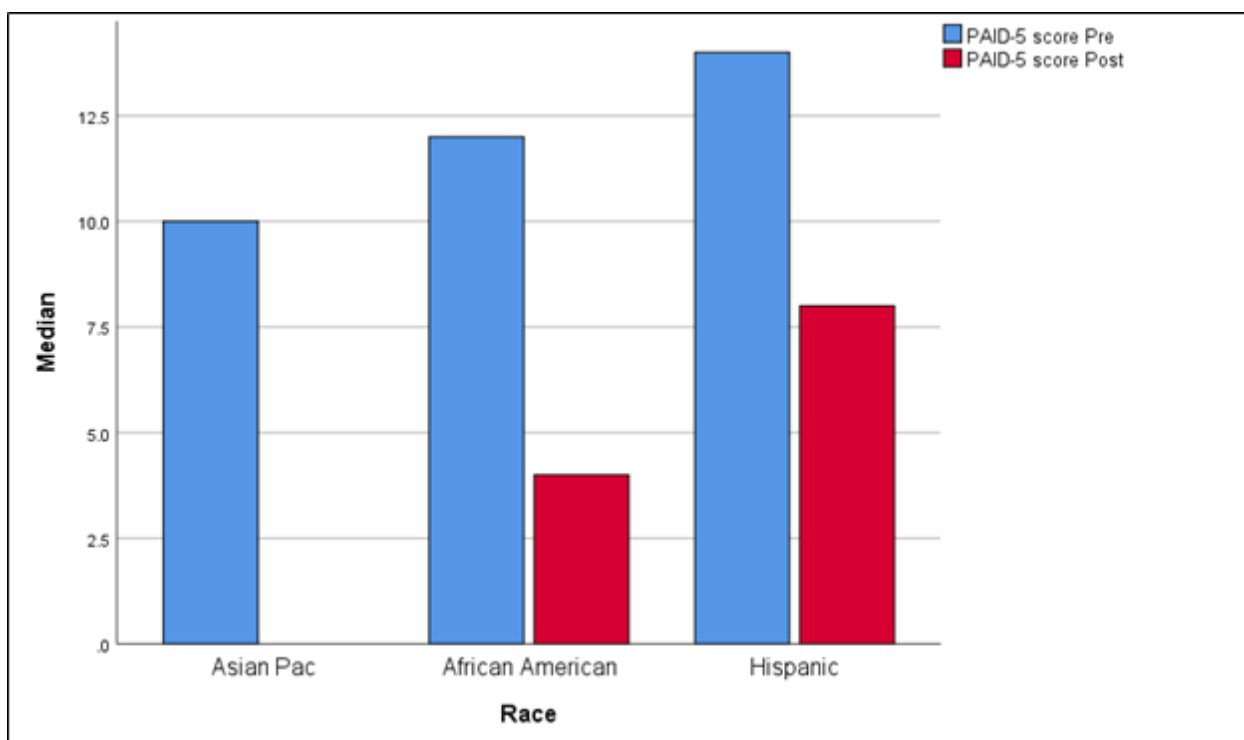
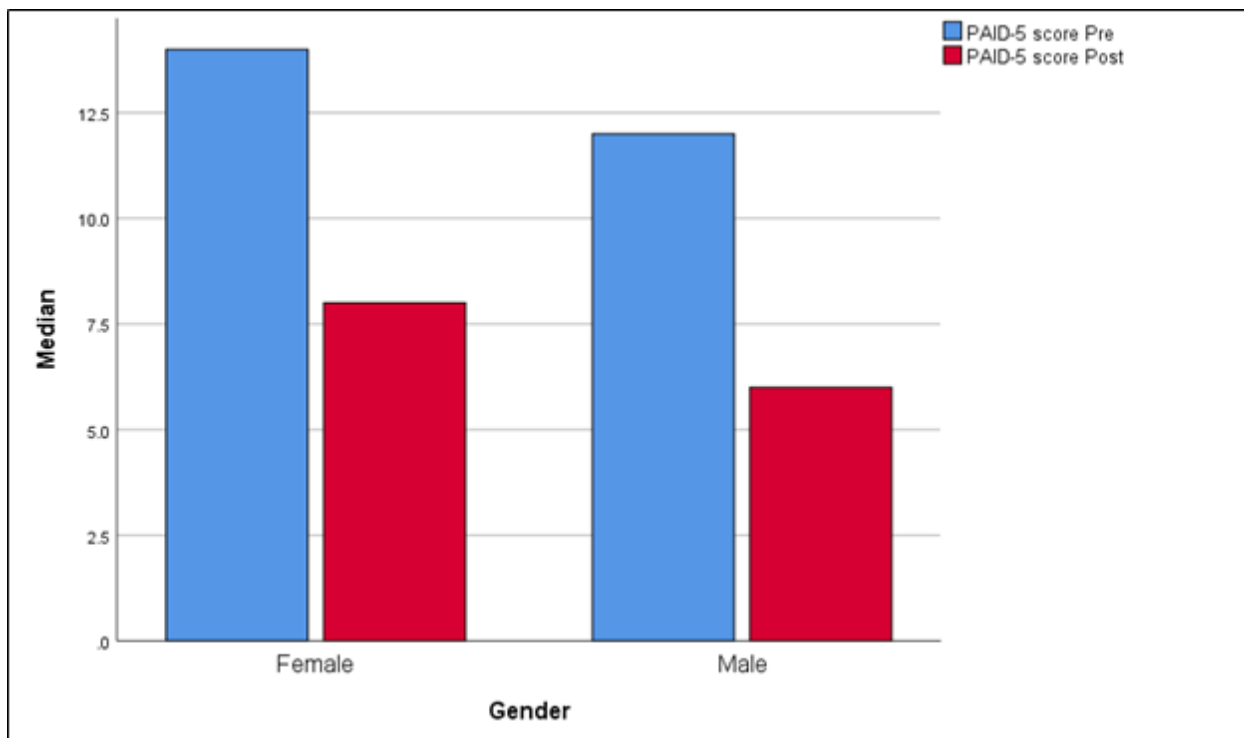
2. How do you plan to use the recommendations from the therapist?

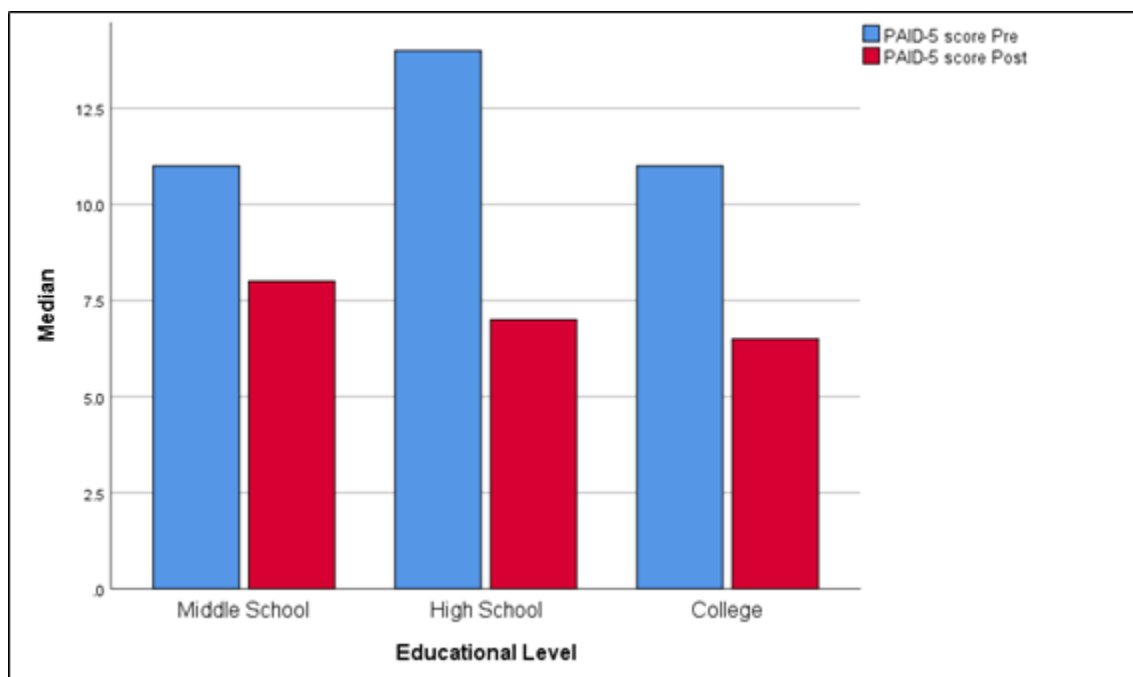
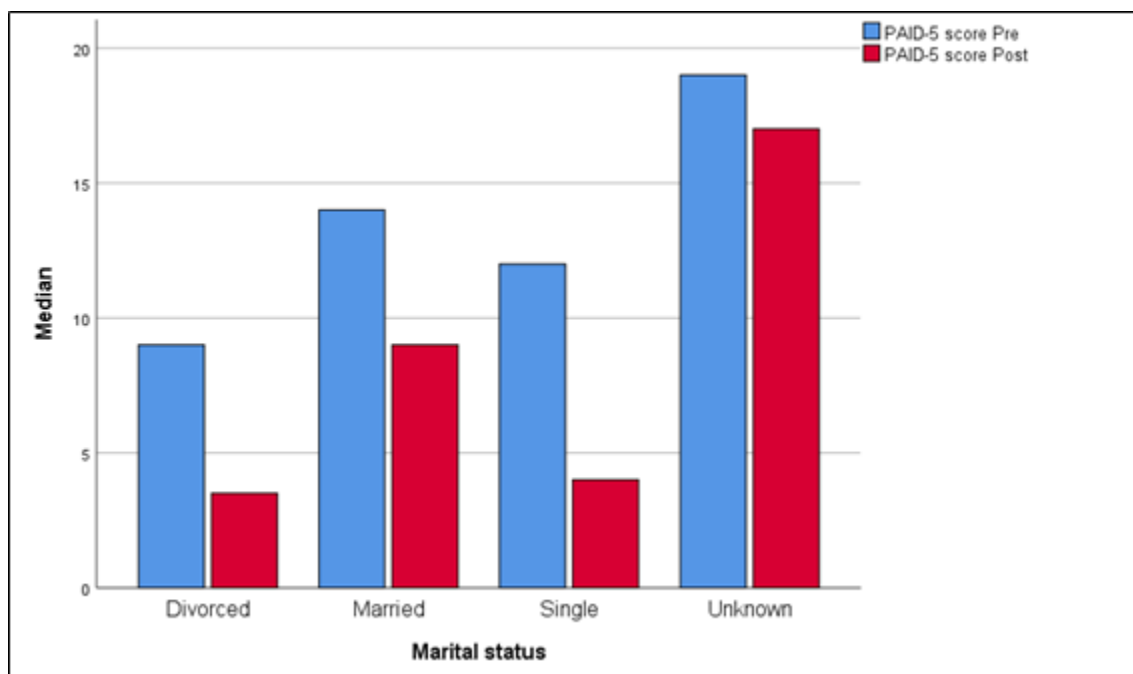
Other Comments:

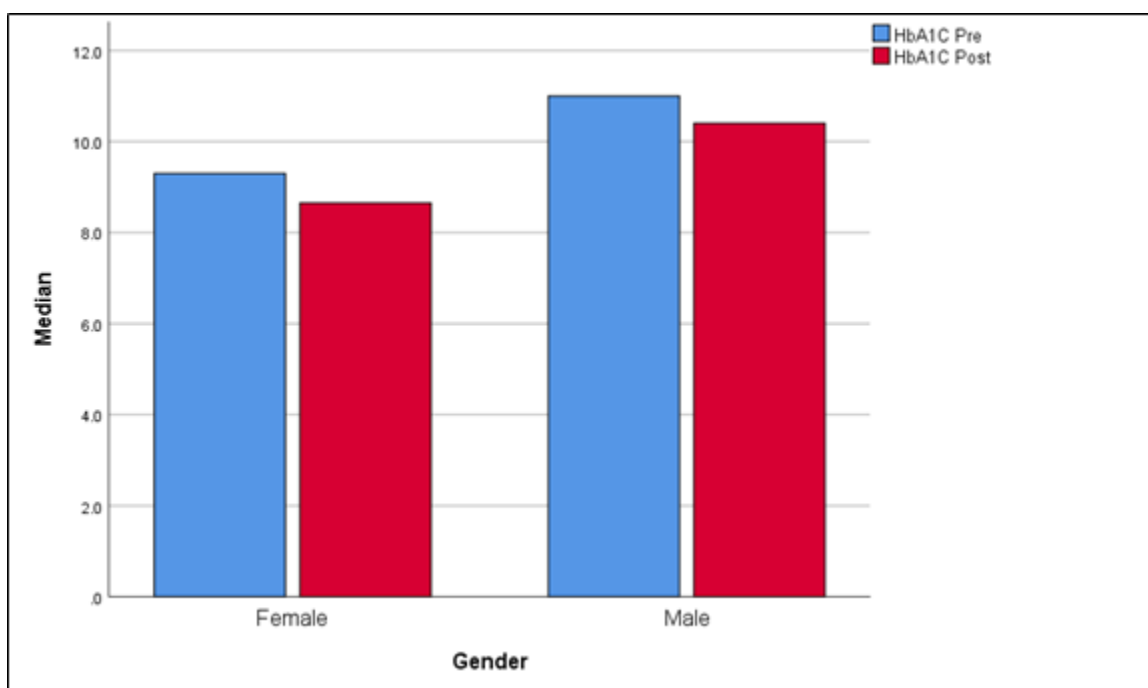
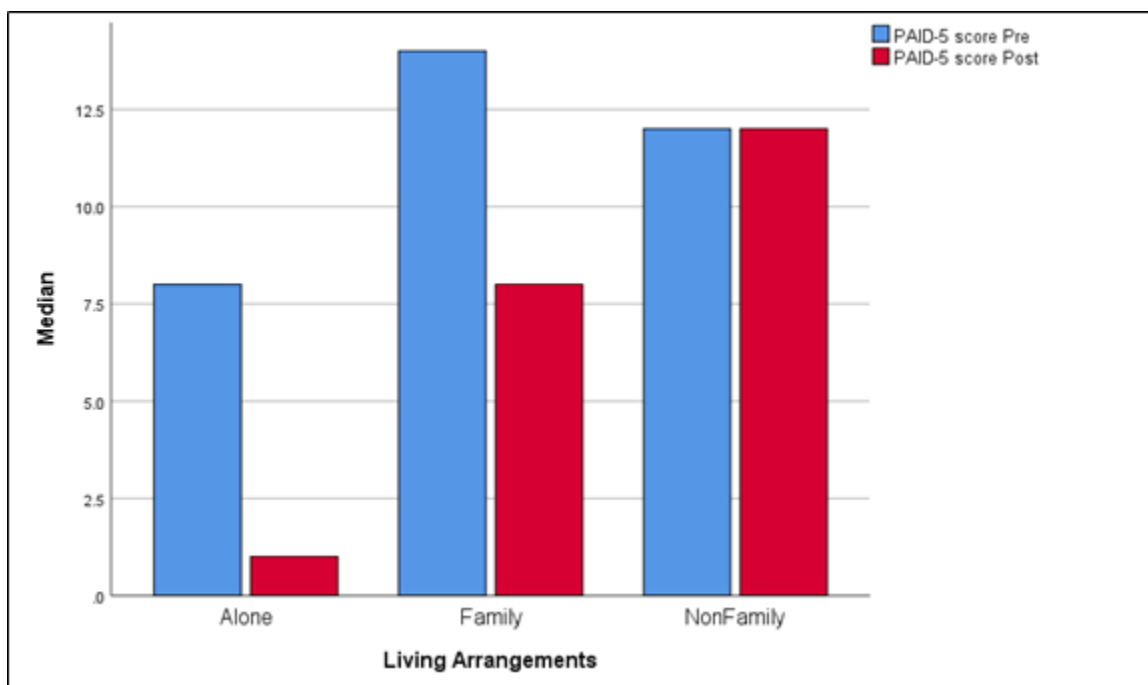
Appendix H: Graphs

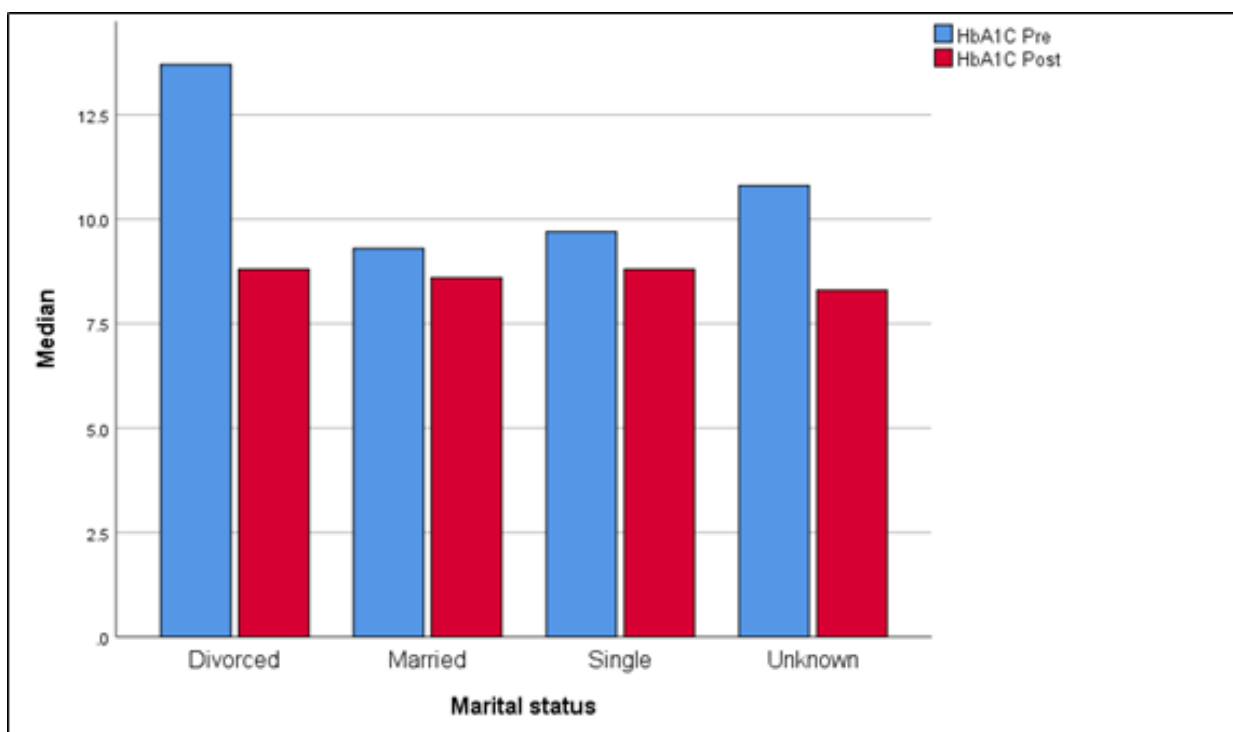
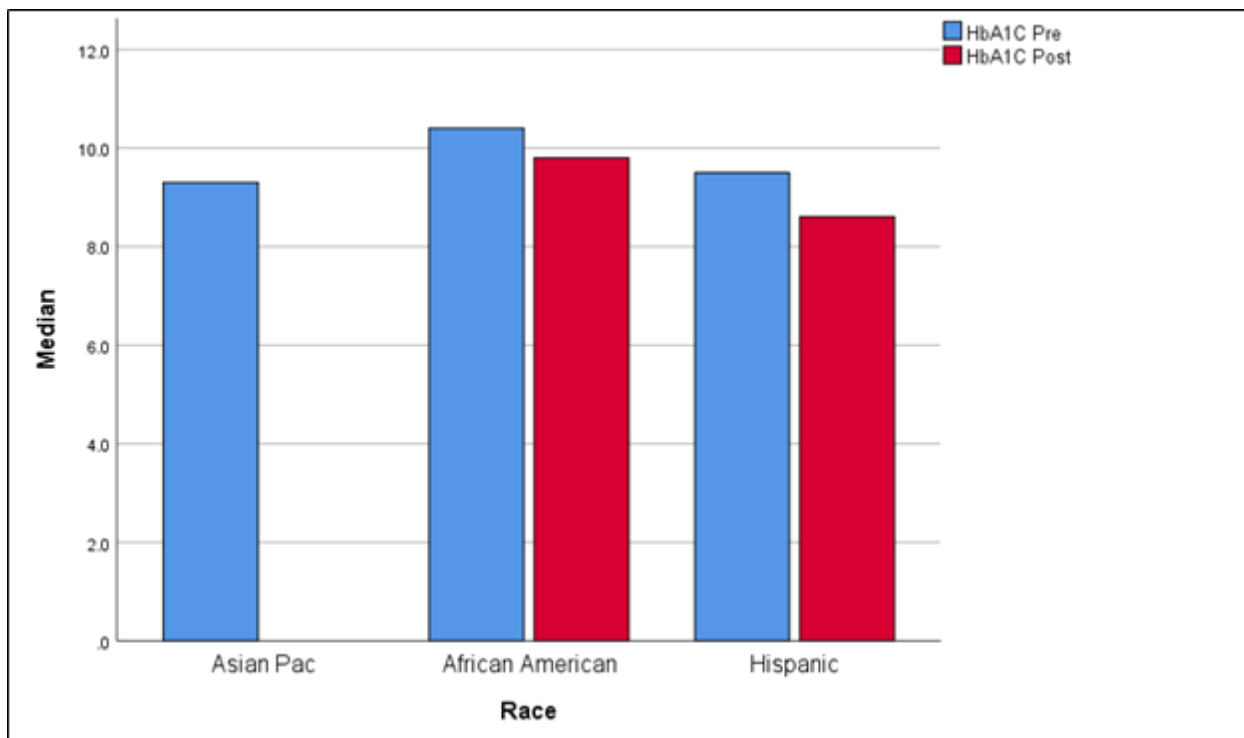


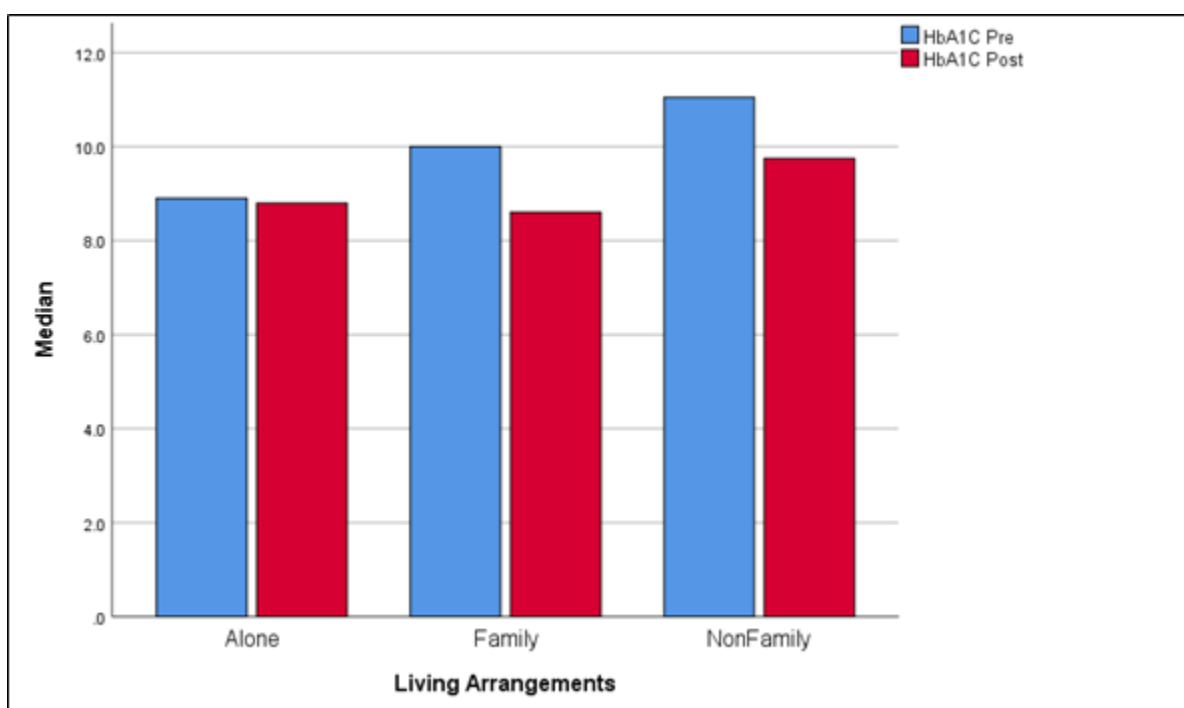
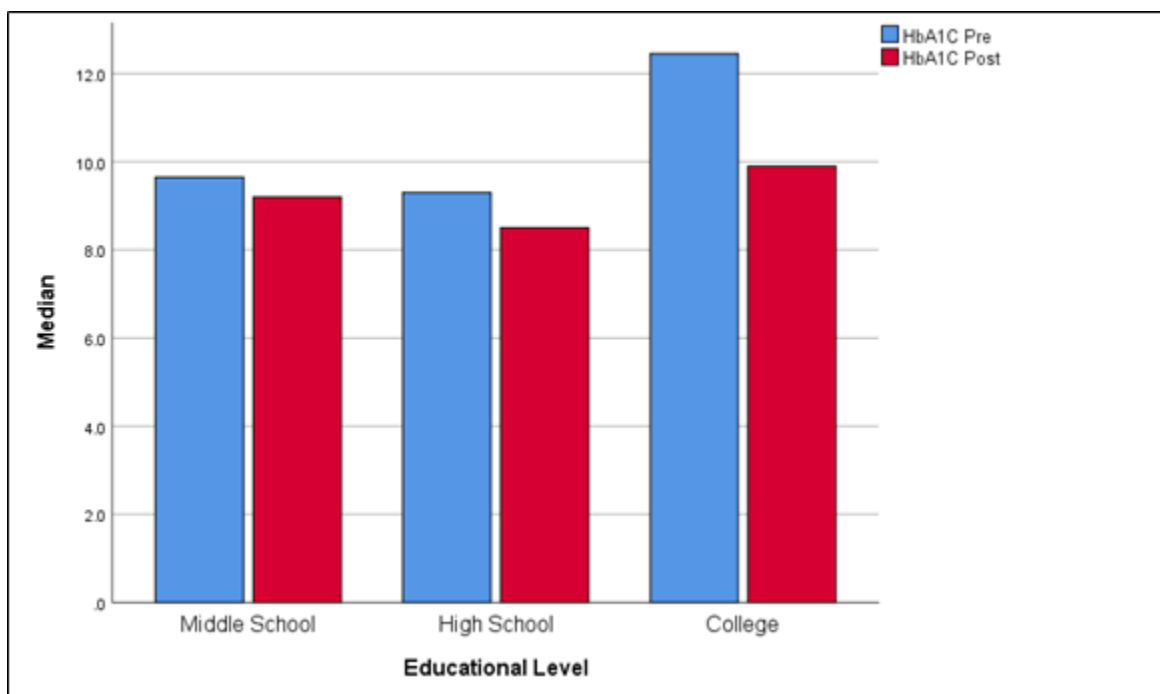












Appendix I: Table of Themes and Validating Quotes

Theme	Patient's quote	Therapist quote
Being normal	<p>"I was happy that I was able to talk in detail to somebody about my issues, and she listened well, and I am applying. This was a change from being always listening to what others have to say. She told me that it is normal to feel worried about diabetes. I realized that I could do better where I am standing." (Participant 1)</p> <p>"Went very well. We talked together for some time, and she suggested things I can do. I now know that it is normal to feel the way I do due to my diabetes. I feel better now." (Participant 8)</p> <p>"The session was very useful. She told me it is normal and okay to feel stressed about my condition. My main problem is with food and the therapist was able to tell me about ways to deal with the problem, without having to experience too much stress." (Participant 11)</p>	<p>"I explored with pt. his core beliefs about diabetes. Pt expressed that there is no way out. The clinician encouraged and challenged pt.'s faulty belief. In this session, the therapeutic focus was on building and establishing trust. The pt. was encouraged to ventilate and ask for help throughout the session. The clinician reviewed with pt. healthy coping skills, such as increasing physical activity and finding things of enjoyment. Pt reports he would try. Pt reports complying with medication and medical appointments."</p>
Useful advice	<p>"I am trying to follow recommendations: eat better, take more natural food, and take remedies. I will try to be positive, tell my family that I love them, and get their support. I will try to keep appointments and follow recommendations from providers." (Participant 1)</p> <p>"Blood sugars are doing much better (170s now, was 171 today) now. The therapist explained everything I have to do, and I am doing much better." (Participant 2)</p> <p>"The session was a useful discussion. Diet, exercise, and medication intake were discussed, I feel better able to control my diabetes." (Participant 15)</p>	<p>"I involved the patient in a brief intervention. Paid-5 score 15. Pt's chief complaint is fear of losing his eyesight. Pt reports he resides with his wife and is trying to maintain a healthy lifestyle, however, is frustrated. Pt has several medical appointments to follow up and has verbally agreed to comply with treatment. I suggested to the pt. to take time out for himself such as taking brisk walks. I reviewed with the patient ways to reduce frustration. Pt was open and receptive to suggestions. I provided supportive listening and educated the benefits of therapy. I encouraged the pt. to seek his social support. Pt reports not having strong social support due to isolation. At the time of the</p>

		session, pt. was engaged in conversation and became tearful."
Working on better coping skills	<p>"Very good. I had sexual dysfunction (ED) from diabetes but am processing and coping with my issues in a positive approach, as suggested by the therapist. My wife is understanding and supportive. The therapist told me how to replace negative thoughts and improve my coping skills." (Participant 10)</p> <p>"It was very good. We discussed diabetes, my family situation, etc. I am now better able to control myself, and am trying to move, and feel positive and less stressed." (Participant 12)</p> <p>"CBT was very useful. I got to talk to someone about my problems in detail. She discussed my problems from diabetes and how to manage them. She told me to think positively and to take one step at a time. We set some short- and long-term goals." (Participant 13)</p>	<p>"Pt. present calm and open to the session. The pt. reports diabetes-related emotional distress. Pt expressed she is complying with medication. However, the patient reports that she is not receiving her prescription through the pharmacy and it has been a struggle. To assist the patient, I would contact the pharmacy with the patient's request on 3 different medications. Therefore, the patient states she has an understanding of how to manage diabetes. Pt. reports that she has seen a nutritionist in the past and is aware of healthy eating options. Pt has also mentioned that she is a child caregiver and does not have time to unwind.</p> <p>Throughout the session, I actively listened to build the level of trust with the patient, and provided unconditional positive regard and warm acceptance.</p> <p>The pt. was educated about the effect of a healthy diet on long-term medical well-being. I referred the pt. to The Harris Center and Catholic Charities for further BH services or to check back with SJC for BH."</p>

Appendix J: Permission to Use TableDiabetes distress article Inbox x

Swapna Thomas <sthomas43@twu.edu>
to christina.rariden ▾

Jan 18, 2021, 11:44 PM



Respected madam,

I am a family nurse practitioner and a student of Texas Woman's University, currently doing a project "looking at ways to address diabetes distress to improve outcomes in type 2 diabetes" as part of my DNP program. I came across your well written article on the topic, which I discussed with my faculty. This email is to request permission to use the table titled "Steps to Meaningful Clinician-patient Conversation" in my project.

Your approval and kind help will be highly appreciated.

Swapna Thomas, FNP
San Jose Clinic, Houston.



Christina Rariden christina.rariden@slu.edu via sluedu.onmicrosoft.com
to me ▾

Jan 20, 2021, 2:31 PM




Hello!

Yes you may use the table, just cite appropriately.

Good luck with your project. It is an important topic.

Kindly,

	<p>Christina Rariden, DNP, FNP-BC, FPMHNP-BC Assistant Professor School of Nursing 3525 Caroline Mall 425 St. Louis, MO 63103 christina.rariden@slu.edu slu.edu peabilliken.com slucare.edu</p>
---	--

Appendix K: IRB Certification

Texas Woman's University
Institutional Review Board (IRB)

irb@twu.edu

<https://www.twu.edu/institutional-review-board-irb/>

August 5, 2021

Swapna Thomas

Nursing - Houston

Re: IRB Not Required for IRB-FY2021-392 Title: Managing patients with diabetes distress: A quality Improvement project

Dear Swapna Thomas,

The above referenced project has been received by the TWU IRB - Houston and it has been determined that this project does not require IRB review.

Project qualifies as Quality Improvement project.

If you have any questions or need additional information, please contact the IRB at irb@twu.edu or refer to the [IRB website](#).

Sincerely,

TWU IRB - Houston